sigmaspectrum

Operator's Manual

35700ABB & 35700BAX

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INTRODUCTION AND SAFETY

Intended Device Use

The SIGMA Spectrum and SIGMA Spectrum with Master Drug Library are intended to be used for the controlled administration of intravenous fluids. These fluids may include pharmaceutical drugs, blood, blood products, antibiotics, nutritional fluids and mixtures of required patient therapy. The intended routes of administration consist of the following clinically acceptable routes: intravenous, arterial, subcutaneous, intrathecal, epidural or irrigation of fluid space. The SIGMA Spectrum is intended to be used in conjunction with legally marked intravenous administration sets and medications provided by the user.

The SIGMA Spectrum and SIGMA Spectrum with Master Drug Library is suitable for many user facility applications such as, but not limited to, hospitals, outpatient care areas, homecare and ambulatory care services. The SIGMA Spectrum and SIGMA Spectrum with Master Drug Library has not been tested or approved for use in motor vehicles or aircraft.

The SIGMA Spectrum and SIGMA Spectrum with Master Drug Library are intended to reduce operator interaction through automated programming, thereby helping to reduce errors associated with complex device programming. Parameter programming requires a trained healthcare professional to confirm the limits and drug therapy parameters in accordance with a physician's instructions.

Related Documents

The following documents also pertain to the Spectrum and Spectrum with Master Drug Library:

- Service Manual P/N 41019
- MDL User Manual P/N 41020

Regulatory Information

Conforms to UL STD 60601-1

Certified to CAN/CSA STD C22.2 NO 601.1-M90

Contacting SIGMA Technical Support

Contact SIGMA LLC for all service information at:

Telephone:1-800-356-3454

Email: techsupport@sigmapumps.com

Conventions

WARNING: Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.

CAUTION: Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate personal injury or property damage. This word is used to also alert against unsafe practices.

Summary of Warnings and Cautions

WARNING: Operation is Limited to Trained and Tested Operators

SIGMA Spectrum operation is strictly limited to trained operators whose competency in safe Spectrum operation and in safe IV therapy practices has been tested and proven. Pump owners have sole responsibility for operator training and testing even when SIGMA personnel assist in training processes.

WARNING: Confirm Safe Operation at Start and Thereafter

Confirm safe, accurate pump operation at start and periodically thereafter by:

- Observe the drip chamber to verify that there is no flow from your fluid container.
- Confirming the drip rate approximates the pump's flow rate during RUN operation.
- Confirming pump settings are as intended.
- Confirming correct: patient, route, dose, time and drug/concentration.
- Regularly assessing the patient's vital signs and IV sitesto ensure that they are in good condition.
- Clinicians are advised to verify the proper route of delivery.
- When using the pump periodic patient monitoring must be performed to ensure that the infusion is proceeding as intended.
- The pump was not designed nor it intended to detect infiltrationsor extravasations.

Never operate the Spectrum unless all of the above safe operations are being practiced.

WARNING: Prevent Inaccuracy

The following can cause flow rate inaccuracies and must be avoided:

- Incompatible brand IV sets and compatible brand IV sets with unusually large or small diameters or unusually stiff materials.
- Operating temperatures outside of 60-90°F for Standard Battery and 60-80°F for Wireless Battery Module.
- Using IV sets longer than is recommended in the Specifications section of this manual.
- Using a dropped, damaged, dirty or wet pump.
- Pressurizing IV bags.
- Positioning IV containers more than 3 feet above or 1 foot below the pump.
- Using Microdrip or Minidrip chambers for flow rate settings greater than 200 mL/hr. Doing so may influence flow rate accuracy and cause nuisance air or upstream occlusion alarms.
- Exceeding 500 mL/hr flow rate settings when using sets with backcheck valves. Doing so may influence flow rate accuracy or cause nuisance upstream air or upstream occlusion alarms. Flow rates above 300mL/hr may cause fluid to be siphoned from the primary container during piggyback operation (see Secondary Infusion).

Note: Upstream occlusion detection is only effective for occlusions present immediately after the start of the pump's run operation. Upstream occlusions caused by non-vented IV sets used with non-vented glass bottles or closed burette air vents cannot be detected because of the very slow-building vacuums resulting from these situations.

WARNING: This equipment is not suitable for use in the presence of a Flammable Anesthetic Mixture with Air or with Oxygen or Nitrous Oxide. (This statement is a requirement of the IEC—60601-2-24 standard. It applies to oxygen enriched environments, such as oxygen tents. It is not meant to apply to patients on breathing tubes.)

WARNING: Follow Epidural Precautions

Epidural administration of drugs other than those indicated for epidural use can result in serious patient injury.

- When administering epidural analgesics, use only catheters specifically labeled for epidural analgesia drug delivery.
- To help prevent accidental infusion of non-epidural drugs, DO NOT USE epidural administration sets that contain injection sites.
- Label the administration container and IV set "EPIDURAL USE ONLY".
- Clearly identify infusion pumps used for epidural administration.
- Use KEYLOCK.

WARNING: Do Not Allow Uncontrolled Gravity Flow

To open the pump door, the IV set's slide clamp must first be closed (thus providing "set-based anti-free flow" protection). Do not open the slide clamp when the door is open or during and after IV set unloading. This can cause dangerous, uncontrolled free flow to occur. During IV container changes, always close the set's slide or roller clamp. When the set is in the pump and the door is closed, the slide clamp can be left open. If gravity flow is to be used, the pump door will be open or the set will be outside the pump. You will need to be sure gravity flow is maintained at the intended rate whenever the pump door is open and when the set is outside of the pump.

WARNING: Disposal

To dispose of this device or the associated administration sets, adhere to local, state, federal and/or other governing regulation.

WARNING: Use the Specified Manufacturer's IV Set Type

This label is located on the top of the pump and indicates the specific type of IV tubing that the pump has been calibrated for. The use of other manufacturer's brands or type tubing could produce pump inaccuracies that could be unsafe for patients.

CAUTION: Use Keypad Lock to Avoid Tampering

See "Operating the Keypad Lock" on page 44.

CAUTION: Follow Neonatal and Pediatric Precautions

- Use 60 drops / 1 mL IV sets.
- Configure the pump with appropriate flow rate, VTBI (Volume To Be Infused), patient weight and occlusion alarm limits (using CONFIGURATIONS/Options mode).
- Prior to connecting to patient, prime set, load set, open slide and roller clamp (if equipped) to avoid possible bolus (.2mL) that would result around door opening/set loading event.
- If the pump door is opened with an IV set connected to a patient and bolusing at door closing must be avoided before closing the door, clamp the set below the lower Y site, connect a syringe to the lower Y site, close the door, open the slide clamp, collect a 0.085mL bolus in the syringe and unclamp the set below the Y site.

CAUTION: Use Sound IV Poles

Mount pumps on IV poles that securely hold the pump.

CAUTION: Service Personnel Must be Trained at SIGMA

Servicing Spectrum pumps is restricted to qualified, SIGMA-trained, service personnel who employ SIGMA authorized parts and procedures. Use of other parts and servicing procedures is prohibited.

CAUTION: Perform Preventative Maintenance Annually

Pumps should be tested for proper performance annually and also whenever damage from drops, fluid intrusion and other causes is suspected. See SIGMA Spectrum Service Manual for complete information.

CAUTION: Do Not Improperly Clean Pumps

During cleaning, do not allow fluid to seep inside pump (especially through front panel door latch holes or back case speaker holes) or severe damage may occur. Wipe on minimal amounts of cleaning fluids, never spray them. Use only SIGMA specified compatible cleaning fluids. Do not autoclave or ETO sterilize pumps.

CAUTION: Be Cautious Near RF Sources

The Spectrum pump meets the electromagnetic compatibility (EMC) requirements as specified in the International Electrotechnical Commission's (IEC) 60601-1-2 (2001-09) standard for emissions and immunity. It is good practice to keep the pump separated away from other equipment, such as hand-held transmitters, cellular phones and electrosurgical equipment that may generate strong radio frequency interference (RFI). Refer to the EMC Immunity Section, Separation Distance, in this manual for recommended minimum distance.

CAUTION: Confirm Audio Operation

When pressing the ON key and all other keys, confirm that an audio beep is heard. If sound cannot be heard, discontinue use of the pump and return to SIGMA for service.

CAUTION: Confirm Display Operation

Regularly observe the pump's display. Discontinue use of the pump and return to SIGMA for service if display abnormalities are observed.

CAUTION: Electric Shock Hazard

Refer servicing to qualified service personnel at your institution or return to SIGMA.

CAUTION: Accuracy

Refer to trumpet curves for flow rate accuracy as a function of short infusion durations.

The upstream occlusion detector may not detect partially occluded tubing. Always check to ensure the IV set's clamp is not closed above the Spectrum pump.

Small bore catheters or needles may cause excessive backpressure at elevated flow rates. Size the catheters according to expected flow rate and fluid viscosity.

CAUTION: Follow Physicians Orders

Federal (USA) law restricts this device to sale or use by, on the order of, or under the supervision of, a physician or other licensed healthcare practitioner.

CAUTION: Single Fault Conditions

A bolus of approximately 0.5 mL may be generated as a result of a single fault condition.

SYSTEM COMPONENTS

The Spectrum with Master Drug Library is comprised of the following components:

Master Drug Library (MDL) - The MDL is a software toolintended to be used by pharmacists to list all medications that would be delivered via the Spectrum Pump, along with associated care areas and infusion parameters for each drug entry.

MDL Transfer - The MDL Transfer is the process by which information in the library is communicated to the pump. There are two methods:

- Transfer from a wireless network connection to a pump using a wireless battery module
- Transfer from a PC via infrared to a pump

SIGMA Spectrum Infusion Pump - The pump and the interface for programming the pump.

Standard Gravity IV Sets - Compatible IV sets with slide clamp used for the door opening.

Figure 1. SIGMA Spectrum Pump

Figure 2. Standard gravity IV sets

with slide clamp(required for door opening)

Spectrum Pump Illustrations

Figure 3. Front View - Door Open

Figure 4. Back View- With Standard Battery (P/N 35724)

Figure 5. Back View- With 802.11b Wireless Battery Module (P/N 35083)

Figure 6. Back View- With 802.11b/g Wireless Battery Module (P/N 35162)

Hardware Labeling

The following is a description of the labels and symbols that appear on the Spectrum pump

	Attention, consult ACCOMPANYING DOCUMENTS (ISO 7010-W001)
	CLASS II EQUIPMENT (IEC 60417-5172)
	TYPE BF APPLIED PART (IEC 60417-5333)
	Direct current (IEC 60417-5031)
	Recyclable, dispose of properly (ISO 7000-1135)
	This is a representation of the Direction of Flow (not to scale). This label appears behind the door of the pump. It is intended to assist the user in determining the direction of fluid flow from the medication container to the patient. The fluid direction is controlled by the pumping mechanism when the door is closed and the pump is in the infusion mode (running).
	Non-ionizing electromagnetic radiation (IEC 60417-5140)

BATTERY COMPATABILITY

There are three battery types:

- P/N 35724 - standard battery
- P/N 35083 - 802.11b wireless module
- P/N 35162 - 802.11g wireless module

The standard battery (P/N 35724) and 802.11b wireless module (P/N 35083) are compatible with all SIGMA Spectrum pumps.

The 802.11g wireless module (P/N 35162) is only compatible with wireless G compatible pumps.

Wireless G compatible pumps are identified by the letter G preceding the serial number on the pump (see Figure 7.). Pumps that do NOT have a letter G preceding the serial number (see Figure 8.) are not compatible with the 802.11g wireless module (P/N 35162).

Figure 7. Serial Number for Pump Compatible with the 802.11b/g Wireless Battery Module (P/N 35162)

Figure 8. Serial Number for Pump NOT Compatible with the 802.11b/g Wireless Battery Module (P/N 35162)

SETTING UP THE PUMP

Unpack the Pump

The SIGMA Spectrum is packaged to provide protection during transportation and storage. When you unpack the pump, remove the Spectrum from the protective anti-static bag, remove the protecting foam end caps, and discard the desiccant package.

A battery tab isolates the battery voltage from the pump during transport and distribution. Remove the battery insulating tab prior to charging the pump's battery or operating the pump. To remove the battery tab, pull the tab straight out from the Battery Pack mounting cavity.

Figure 9. Battery Tab

- Save all packaging materials for reuse. This is advised in the event product repair or warranty replacement is necessary.
- Fully charge the battery prior to use.

AC Power Adaptor

WARNING: Only use the power adaptor specified for this equipment. Using other power adaptors may cause personal injury or damage to equipment.

When plugged into a powered wall outlet, the power adaptor charges the pump's battery. The power adaptor uses a locking cord connection to prevent inadvertent disconnection.

NOTE: Repeated drops of power adaptors on floors will cause them to malfunction. As with all electronic devices, drops should always be prevented.

Power Adaptor Protector

The Adaptor (power supply) side of the A.C. Power Adaptor is equipped with a Protector (P/N 45742). The Protector is a plastic enclosure which snaps onto the Adaptor. The purpose of the Protector is to protect the Adaptor from damage during use in a hospital environment. The A.C. Power Adaptor with the Protector can be used on a powered outletreceptacle and Pole Mount power strip receptacles. The Protector comes installed with the pump. The Protector cannot be removed from the Adaptor once it is installed. The Protector can be ordered separately as an accessory for installing on old A.C. Power Adaptor. A separate instruction bulletin on how to install the Protector accompanies the Protector.

Cleaning the Power Adaptor

The Protector is compatible with the cleaners mentioned in this Operators manual. For the methods of cleaning and compatible cleaners that can be used on the A.C. Power Adaptor with Protector, see "Cleaning and Storage" section, beginning on page 53.

Connecting the Power Adaptor

To engage the power adaptor:

1. Align the arrow on the power adaptor cord with the arrow on the connector identified as the external power adaptor connection (on the back of the SIGMA Spectrum pump).
2. Insert the power adaptor module into the appropriate powered outlet receptacle.

   The green LED on the power adaptor is on when the adaptor is plugged into a powered wall outlet. On the Spectrum Pump display, a plug symbol appears if the power adaptor is working properly when the pump is in operation.

Removing the Power Adaptor

NOTE: Improper removal may damage the power adaptor.

To remove the power adaptor, grasp the handle of the Protector and pull it back from the receptacle in a straight direction.

Figure 10. Pull the adaptor straight out

Do not pull the adaptor at an angle. This could bend the prongs. Do not pull the cord to unplug the adaptor from the receptacle. Improper twisting or pulling of the connector or cord may damage the power supply.

Charging the Battery

When the SIGMA Spectrum is connected to the AC Power Adaptor and the adaptor is plugged into a powered outlet receptacle, the pump's Standard Battery Pack or Wireless Battery Module will be charged to full capacity. It is not necessary to turn the pump on.

Refer to "APPENDIX G - Icons" section, beginning on page 91 for a listing of the symbols used and their description.

Configuring User Options

The Spectrum pump has two sets of configuration options:

- User options
- BioMed options

NOTE: For a description of the BioMed options, refer to the SIGMA Spectrum Service Manual.

User Options

To access the User Options menu:

Software version 6.02.00 and earlier

From the Care Area selection screen:

1. Press the **HELP** softkey.

2. Press the **OPTIONS** softkey.
3. Select **User Options** from the options list and press **OK**.

Software version 6.03.01 and later

From the Care Area selection screen:

1. Press the **OPTIONS** softkey.
2. Select User Options from the menu and press ok.

From the RUN or STOPPED screen:

1. Press the **OPTIONS** softkey.

The User Options menu has three categories:

- Alarm Settings
- Display Settings
- View Information

Alarm Settings

- **Audio Volume** – The audio volume of the pump has three levels; LOW, MEDIUM, and HIGH.
- **Audio Tone** – set the type of alarm tone that sounds: Short or Long.
- **Standby Delay (hr:min)** – Set the length of time to keep the pump in standby (or Hold) after setup of the infusion has completed. Settings are from 00:01 to 99:59 (hr:min). Setting the value to 00:00, or Infinite, results in an infinite Hold period.
- **Near Empty Alert** – When enabled, a callback alert is generated when less than 30 minutes of infusion remain. If the initially programmed infusion is less than 30 minutes, the alert shall not be generated regardless of the setting.
- **Down Stream Pressure Limit** – Pressure levels are selectable from three levels: LOW (6 psi ±4 psi), MEDIUM (13 psi ±6 psi), and HIGH (19 psi ±9 psi).

Display Settings

- **Run Screen Options** – Each of the items in this list may be turned ON or OFF. If enabled, they are included in the alternating screens that are displayed while the pump is running.
  - Audio level indicator – shows L, M, or H (as selected in Audio Volume)
  - Rate mL/hr – shows the mL/hr infusion rate of the current delivery
  - Dose rate – shows the dose rate of the current delivery
  - mL VTBI – shows the remaining Volume To Be Infused, in mL
  - Time (hr:min) – shows the time remaining in the current infusion, in hr:min format
- **Display Adjust**
  - Backlight Level – The display backlight level may be adjusted or turned OFF. The backlight consumes approximately 400 mW when set to maximum brightness; therefore, battery life is maximized when the backlight is set to OFF.
- **Setup Options**
  - Concentration confirmation – Setting this option to ON results in a prompt that requires the operator to confirm that the concentration value selected from a list of concentrations or a user-entered variable concentration is correct.

- 'New Patient?' Prompt – When the pump is turned on and programmed infusion data exists in memory, a screen is displayed asking the operator if the intended use for the pump is for a New Patient. Answering YES to this prompt clears the existing infusion data, answering NO retains the data and allows the operator to resume the infusion. Setting this option OFF disables this screen.

View Information

- **Pump Information** – The pump information screen has the following read-only information that either the user (clinician) or Bio-Medical Engineer may find useful. From the Pump information screen, press the **sw info** softkey to display the Software Version screen, which show the versions of the individual software components that are installed.
  - SW Version
  - Sharp build
  - PIC build
  - CPLD build
  - SmartBatt Charger build
  - Network Module build
  - Serial number – The serial number assigned by SIGMA for tracking and device history.
  - Tube type – the name of the IV tube set manufacturer that the device is calibrated for use with.
  - Wireless Module Type
- **Library Information** – The library information screen identifies the name of the Active Drug Library in pump memory as well as the date modified, version number, and format indicators.
- **Show Clinical Advisory** – If the current infusion has a clinical advisory associated with it, selecting this option will display the advisory. If the current infusion does not have a clinical advisory associated with it, this option is not selectable and appears in grey text in the display.
- **Infusion Information** – The infusion information screen identifies the infusion-specific primary and secondary bag parameters that are not otherwise displayed on the setup screen. The information includes the following information for each bag (if programmed): audio level, near empty alert status (primary only), pressure setting, KVO rate (primary only), and primary siphoning alert or secondary complete alert status (secondary only).
- **History Log** – Selecting this option provides access to the event log. Available options for viewing the log are listed below.

  NOTE: Access to this option is provided only when the pump is not running (delivering). If the pump is running, this option is not selectable and appears in grey text in the display.

  - View History Log – select this option to view the entire history log on the pump screen.
  - View System Error Log – select this option to view only the system errors recorded in the history log.
  - View Drug Error Log – select this option to view only the events associated with programming an infusion; including any drug limits that may have been exceeded during setup.
  - Dump History Log – select this option to send the entire history log out of the pump via the IrDA port (refer to the Logging section of the SIGMA Spectrum Service Manual).

OPERATIONAL OVERVIEW

The following sections provide a high-level overview of how to setup, program, and operate the Spectrum pump. For detailed instructions, refer to these sections:

- "Preparing the Pump and IV Sets" section, beginning on page 19
- "Programming the Pump" section, beginning on page 21
- "Pump Operation" section, beginning on page 43
- "Alarms" section, beginning on page 46

Starting a New Infusion Using the Drug Error Prevention (DEP) Mode

1. Power on the pump.
2. Load the IV set.
3. Select your care area.
4. Select a drug.
5. Select a concentration.
6. Select primary or secondary bag.
7. Enter and **OK** all required values on the setup screen.
8. Push **RUN/STOP** to start the infusion.
9. Check and confirm proper flow.

Starting a New Infusion using the Basic Mode (for drugs not in the drug library)

1. Select **BASIC** from the Care Area library.
2. Select primary or secondary bag.
3. Select a dose mode (default is mL/hr).
4. Enter and **OK** all required values on the setup screen.
5. Push **RUN/STOP** to start the infusion.
6. Check and confirm proper flow.

Secondary Infusions

1. Lower the primary bag at least 20" below the secondary bag.
2. Stop the pump if it is running.
3. Press the **REVIEW/PROGRAM** softkey.
4. Press the **PROGRAM SECONDARY** softkey.
5. Select the drug for the secondary infusion.
6. Push **OK** to select/confirm the secondary bag.
7. Enter all required values on the setup screen.
8. Push **RUN/STOP** to begin secondary infusion.
9. Check the flow and confirm that drops are falling in secondary and not the primary drip chamber.

PREPARING THE PUMP AND IV SETS

1. Mount the pump on an IV pole.
2. Plug the pump'sAC Adapter into a powered outlet receptacle, if available.

   NOTE: It is recommended that the Spectrum pump's AC Adapter be plugged into a powered outlet receptacle whenever possible.

3. Select the IV set.

   Select only IV sets made by the manufacturer listed on top of the pump. IV sets must be of standard stiffness and diameter. Performance can not be achieved using stiff, large, or small diameter tubing. Contact SIGMA for compatible standard IV set lists and for special SIGMA blood, nitroglycerin and lipid sets.

   NOTE: Pumped-on tubing should not be re-loaded into the pumping channel (to avoid nuisance alarms and to maintain flow rate accuracy).

4. Prepare IV fluid containers and prime IV sets:
   a. Position roller clamps below the pump.
   b. Position slide clamp near the keyhole at the top of the pump.
   c. Invert bags that need to be mixed (rather than shaking them).

   NOTE: Warming IV solutions to room temperature before use will reduce nuisance air-in-line alarms.

   d. Fill drip chambers approximately halfway.
   e. Use standard gravity IV set priming technique to purge air from sets and all Y sites.

Loading an IV Set

WARNING: The pump indexes when the set's slide clamp is removed from the pump's keyhole. This propels fluid (maximum of .1 mL) in the IV set in the direction of flow and possibly to the patient. This occurs if the administration set is loaded in the pump and a patient is connected to the administration set.

1. Insert the slide clamp into the keyhole (loading point #1) and press down until the door opens.
2. Load the IV set tubing into the tubing channel:
   a. Load the tubing from the top to bottom of the tubing channel.
   b. Make sure the tubing is taut.

c. Push the tubing into loading point #2 and then loading points #3 and #4.

The tubing is properly loaded when the screen displays a green bar and a check mark.

3. Close the door by pressing the upper and lower corners near the door hooks.
4. Open the slide and roller clamps.

Unloading an IV Set

1. Close the roller clamp and push the slide clamp into the keyhole until the door opens.
2. Pull the tubing out from the bottom of the pump towards the top.

NOTE: Be sure to prevent free flow whenever the pump door is open and when the set is out of the pump. This is accomplished by having the set's slide clamp or roller clamp fully closed or by partially opening the roller clamp to achieve gravity flow.

NOTE: When changing IV sets or containers always keep the roller clamp fully closed (except when following standard gravity set priming procedures).

Preparing the Pump for a Secondary Infusion

If the infusion is to include both a primary and secondary bag and IV set, set up the bags and IV using the following instructions:

1. Prepare primary and secondary bags and IV sets.
2. Use a primary set with an upper Y site and backcheck valve.
3. Connect the secondary set to the primary set’s upper Y site.
4. Using a drop hook, lower the primary bag approximately 20 inches below the secondary bag to provide the secondary bag with a gravity advantage. This causes the primary set’s backcheck valve to close, which ensures secondary flow. When the secondary bag empties, the primary backcheck valve opens and primary fluid begins to flow.

PROGRAMMING THE PUMP

The SIGMA Spectrum Pump provides two main options for controlling infusions:

- **Drug Error Prevention (DEP) Mode** - This mode uses predetermined dosing information stored in the Master Drug Library to control the dose, rate, volume, time and other infusion parameters for specific drugs. This mode protects against human errors that could cause Adverse Drug Events.
- **Basic Mode** - This mode allows you to manually specify the dose, rate, volume, time and other parameters for the infusion. Note, however, that the basic mode can not detect human errors.

Keys Used to Program and Operate the Pump

Key	Description
ARROWS	Press to advance cursors and select alternate choices.
BACK	Press to go back to the previous screen.
BASIC	Press to acesses the mL/hr setup (bypassing the Drug Error Prevention system). From BASIC, dose rate modes and Multi-Step modes may also be selected.
BOLUS	Press to access the Bolus setup without stopping the pump.
CLEAR	Press to erase the highlighted entry.
CLEAR PROGRAM	Press to selectively clear primary mode, secondary mode, or both.
CLR STEP	Press to clear one step of Multi-Step Programming Mode.
EDIT	Press to change the flush volume on the flush setup screen (software version 6.03.01 and later) and on the priming volume screen (MDL version 6.05.00 and later).
HOLD	Press to place the pump in standby mode.

Key	Description
LETTERS	Press numeric keys once, twice, or three times to select corresponding letters.
MULTI-STEP	Press to access the Multi-Step Programming Mode.
OK	Press to confirm entries and advance cursors.
ON/OFF	Press to turn the pump on or off.
OPTIONS	Press to select additional pump features.
PROGRAM SECONDARY	Press to set up a secondary infusion.
RESET	Press to reset the multi-step and cyclic TPN programs to the start.
REVIEW	Press to view the setup screen without stopping the pump.
REVIEW PRIMARY/REVIEW SECONDARY	Press to to view and edit values in the setup screen.
REVIEW PROGRAM	Press to display the setup screen when pump is stopped.
RUN/STOP	Press to start or stop the infusion.
SETUP	Press to start programming.
SILENCE	Press to quiet the audio alarm for 2 minutes. Additionally, any key can be pressed for silence.
SOFTKEYS	The top row of keys on the keypad are non-labeled keys with various functions depending on what is displayed above them.
TAPER DOWN	Press to enable a cyclic TPN program to taper down automatically.
TITRATE	Press to change the flow rate without stopping the pump.

Activating a Drug Library

The pump must be on and in the idle state (not running) for the new drug library to be loaded automatically to the pump.

The pump screen displays the status bar as the library is being installed. A confirmation screen will be displayed when the download is complete. Press **OK**.

If the pump is running, the DL image may appear in the upper right corner next to one of the wireless icons indicating that a new drug library is now available.

To see the new library that is available from the run screen

1. Press the **OPTIONS** softkey.
2. Use the arrow buttons to select **VIEW INFORMATION** and press **OK**.
3. Use the arrow buttons to select **Library Information** and press **OK**.

   The Library Information screen displays the current active drug library information and the queued (new) drug library that is ready to be activated.
4. Press the **EXIT** softkey to return to the run screen.
5. Stop the pump and clear the infusion program to load the new drug library that is available.

Figure 11. Library Information

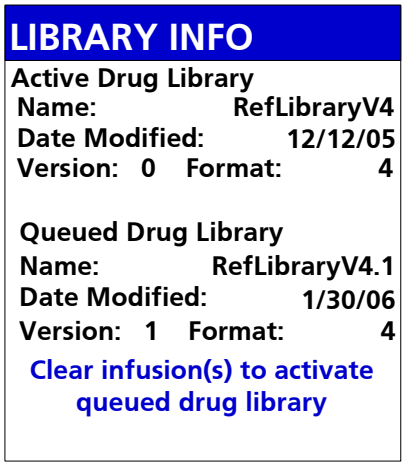
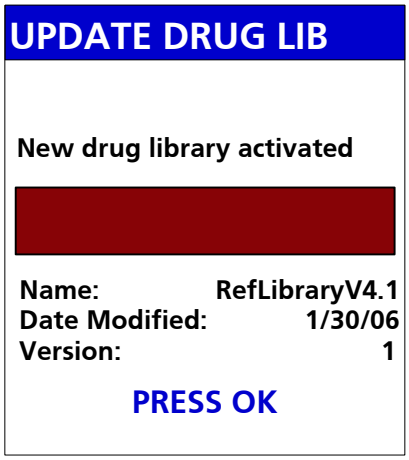
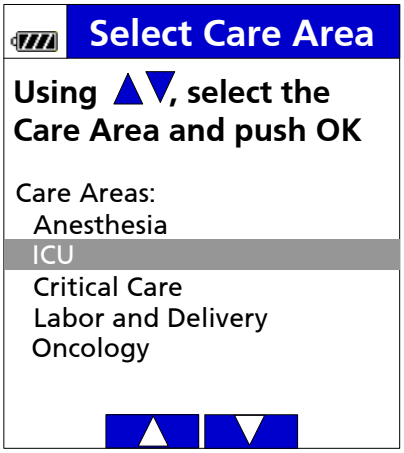


Figure 12. Library Update



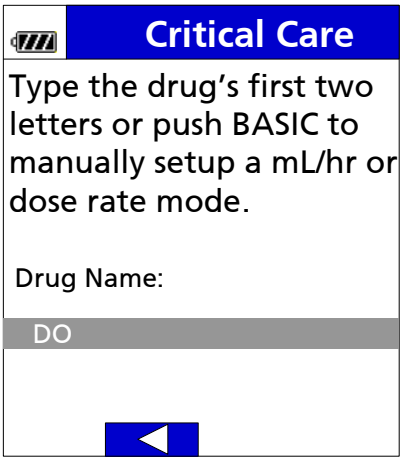
Programming the Pump Using the Drug Error Prevention Mode

1. Press the **ON/OFF** button to turn the pump on.
2. Use the arrow keys to select the care area (nursing area) and press **OK**.

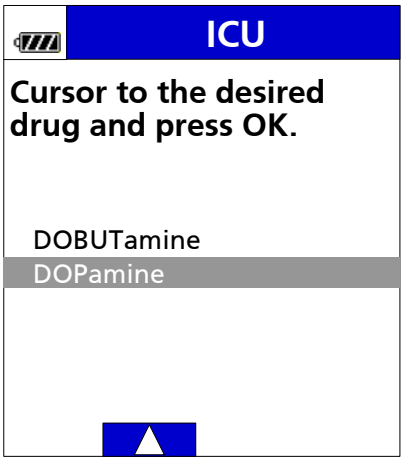


3. Select the drug from the MDL:

   a. Using the keypad, type the drug's first two letters and press **OK**. All drugs beginning with those two letters will appear. Press the key repeatedly to cycle through letters.



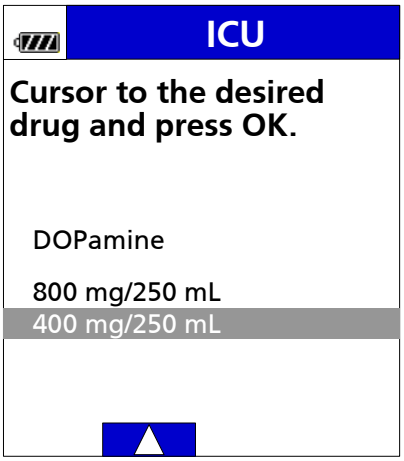
   b. Use the arrow keys to scroll to the desired drug and press **OK**.



4. In software versions 6.03.01 and later, drug modifers are a feature that can be enabled in the MDL. Scroll to the desired modifier and press **OK**.

   NOTE: If a modifier is selected, an (*) icon will display next to the drug name on the pump running screen indicating the use of a modifier. A drug modifier is assigned to a drug in the MDL to identify a specific therapy or application for that drug.

5. Select the correct drug concentration (if more than one is offered) and press **OK**.

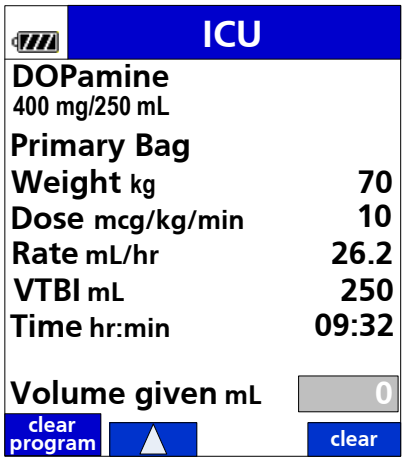


Once a concentration is selected, a dialog appears prompting confirmation of the selected drug concentration. Press **yes** to continue or **no** to reselect. Note that the confirmation dialog appears only when you select from a list of concentrations or if you are entering a concentration manually to a drug that has been assigned a "variable" concentration in the Master Drug Library (MDL).

6. Use the arrow buttons to indicate whether you are setting up the primary or secondary bag and press **OK**.

NOTE: The bag selection prompt does not appear if the selected drug has been specifically assigned to the primary or secondary bag,or as a multi-step infusion in the MDL.

7. Review the parameters for the drug that appear on the setup screen.



8. Change the parameters as needed and press **OK** after each entry.

NOTE: If Weight Confirmation is enabled (set up in the MDL) the pump will require that the patient weight parameter is re-entered into the pump. Both entered values must match to confirm patient weight.

You may receive a popup error if you exceed the dose rate limits defined in the MDL for the drug.

Version 5.02.03 and earlier versions	Version 6.01.00 and later
Soft dose rate limits may be exceeded by pressing **OK** twice (once to enter the value and again to accept the limit warning) thereby providing a double confirmation.	**Soft dose rate limits** may be exceeded by pressing **OK** followed by pressing the **YES** softkey to accept or the **NO** softkey to decline the dose rate displayed in the dialog box.
Hard dose limits can not be exceeded. Reset rates within hard limits.	**Hard dose limits** can not be exceeded. Reset rates within hard limits.
N/A	Rate advisory – dose or mL/hr rate entered is increased or decreased by a % (set in Master Drug Library) above or below the current rate. Press **YES** to accept or **NO** to decline the change displayed in the dialog box. In BASIC mode the default rate advisory is set at 500% and cannot be changed. The rate advisory will be 500% if the selected care area name contains "Anesthesia" or "OR"

9. After you have OK'd each of the parameters, select one of the following actions:

   - To start the infusion, make sure the slide clamp is open and press **RUN**.
   - To put the pump in standby mode, press **HOLD**.
   - To set a delayed start, press **D.RUN** (software version 5.02.03 and earlier).
   - To set up a secondary infusion, press **SETUP**. For version 6.01.00 and later, press **PROGRAM SECNDRY** to setup a secondary infusion.

   For instructions on setting up a secondary infusion, refer to "Setting up a Secondary Infusion" section, beginning on page 29.

10. If you pressed **RUN** to start the infusion, check the flow and confirm that all clamps are open, there are no kinks in the tubing, and drops are flowing. If everything is flowing properly, push the **YES** softkey.

    NOTE: Confirmation that drops are flowing is required for software versions 6.01.00 and later.

The run screens appears indicating that the infusion is running.

Programming the Pump Using the Basic Mode

Software version 6.01.00 and later

1. Press the **ON/OFF** button to turn the pump on.
2. If the previous setup needs to be erased, press **YES soft key** when prompted "New Patient?".
3. Use the arrow keys to select the care area (nursing area) and press **OK**.
4. Using the keypad, type the lettters **BA**, select Basic, and press **OK**. Use the arrow buttons to indicate whether you are setting up the primary or secondary bag and press **OK**.
5. Select **mL/hr** or use arrow softkeys to scroll through dose rates, and press **OK**.
6. If a dose rate is chosen, enter drug concentration and diluent (mL) values.
7. Enter the dose or flow rate value, and press **OK**.
8. Enter the VTBI (Volume To Be Infused) in mL, and press **OK**.
9. Confirm the computed infusion time.
10. Confirm the Volume Given mL value or press **CLEAR** to erase it.

    NOTE: VTBI counts down to zero, while volume given counts from zero up.

11. Press **RUN** to begin the infusion.
12. Check flow displays for rates less than 25 mL/hr in software versions 6.01.00 & 6.02.00. In software versions 6.03.01 and later, check flow displays for all rates:

    - Press **YES** if drops are flowing, all clamps are open, and there are no kinks in the tubing.
    - Press **NO** if no drops are flowing. Open all clamps and unkink the tubing. Confirm all infusion parameters are as intended.

13. Review or reprogram the primary infusion as needed:

    Running

    - Press the **REVIEW** softkey to view infusion information and clear volume given mL.

    Stopped

    - Press **REVIEW/PROGRAM** softkey to display setup screen and change any value.
    - Press **PROGRAM SECNDRY** softkey to program secondary infusion.

Software version 5.02.03 and earlier

1. Press the **ON/OFF** button to turn the pump on.
2. Press **BASIC**.
3. If the prior setup needs to be erased, press **CLEAR ALL**.
4. Select primary or secondary bag, and press **OK**.
5. Select **mL/hr** or use the arrow softkeys to scroll through dose rates, and press **OK**.
6. Enter the flow rate value, and press **OK**.
7. Enter the VTBI (Volume To Be Infused) in mL and press **OK**.
8. Confirm the computed infusion time.
9. Confirm the Volume Given mL value or press **CLEAR** to erase it.

   NOTE: VTBI counts down to zero, while volume given counts from zero up.

10. Press **RUN** to begin the infusion.
11. Confirm all infusion parameters are as intended.
12. Review or reprogram the primary infusion as needed:

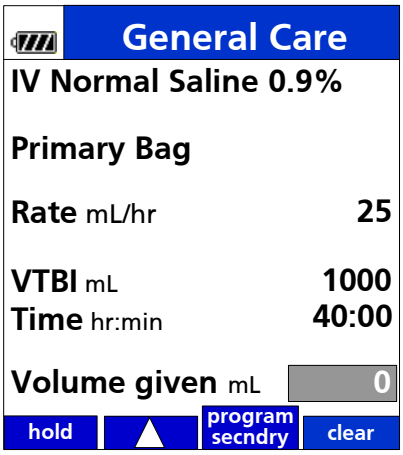
    Running and Stopped - Press **REVIEW** softkey to view and or change highlighted value and clear volume given mL.

Setting up a Secondary Infusion

Software version 6.01.00 and later

1. Make sure you have prepared the pump for a secondary infusion, using the steps in “Preparing the Pump for a Secondary Infusion” section, beginning on page 20.
2. Follow the steps for programming the primary bag infusion as described in either “Programming the Pump Using the Drug Error Prevention Mode” section, beginning on page 24 or “Programming the Pump Using the Basic Mode” section, beginning on page 28.

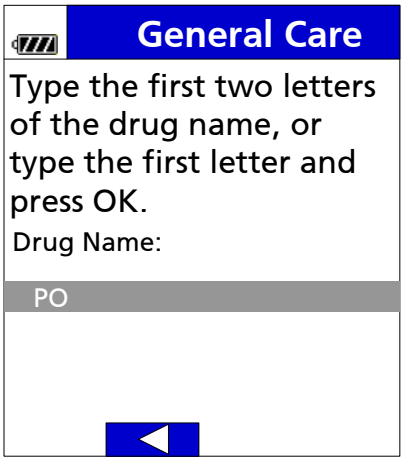
3. When you have finished programming the pump for the primary infusion and before you run the infusion, press **PROGRAM SECNDRY** softkey to begin programming the secondary bag.



4. If the drug is to be delievered using the DEP, select the drug from the MDL:

   NOTE: The drug must be pharmacy / hospital-approved for delivery as a secondary line.

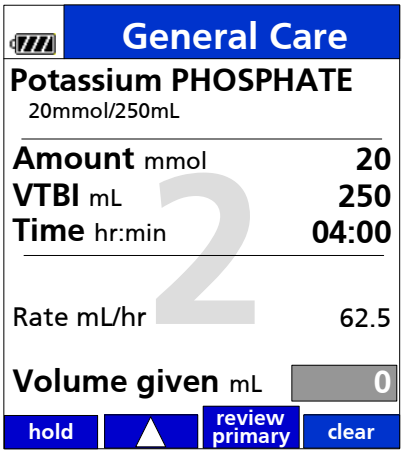
   a. Using the keypad, type the drug's first two letters and press **OK**. All drugs beginning with those two letters will appear.



b. Use the arrow keys to scroll to the desired drug and press **OK**.

5. Press **OK** to select secondary bag or use the arrow softkeys to change to primary bag.
6. Confirm the values on the setup screen:
   a. Confirm the drug and concentrations are correct (if selected).
   b. Enter all required data, and press **OK** after each entry.
   c. To avoid infusing residual amounts of the secondary container at primary flow rates, be sure to properly set the secondary VTBI value. Secondary VTBI should equal secondary bag volume.

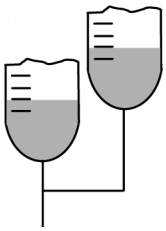
NOTE: A "watermark" indicator is displayed behind the parameter data to help distinguish the secondary (2) setup screen from the primary (1) setup screen. This watermark does **not** appear on primary-only infusions.



7. Press **RUN** to begin the secondary infusion.
8. Confirm the flow from the secondary drip chamber.
   - **YES** – Secondary infuses as programmed until completion with automatic transition to primary.

- **NO** – Hang secondary bag above primary bag, confirm secondary clamp is open and flow from the secondary container, then press the YES or NO softkey.
  - YES – Secondary infuses as programmed until completion with automatic transition to primary.
  - NO – Apply clamp to primary line above upper Y site, and press **OK** to confirm primary is clamped.

The "two bag" icon denotes the secondary is running.



9. If primary line is clamped, the secondary infuses until completion. The rate will decrease to a KVO- keep vein open rate with alarm.
10. Press **STOP**.
11. Press the **SECONDARY** softkey to return to the secondary setup. This allows reprogramming of the secondary infusion.
12. Press the **PRIMARY** softkey to return to the primary infusion, then remove clamp from primary and press **OK** to begin primary infusion.
13. Confirm flow from primary drip chamber (**YES/NO**).
    - YES – Primary infuses as programmed.
    - NO – Close clamp on secondary line. Press **OK** to confirm secondary line is clamped.
14. Upon completion of the secondary infusion and once the transition is made to the primary infusion, a "one bag" icon shall replace the "two bag" icon on the run screen.

NOTE: Upon completion of the secondary infusion, the clamp on the secondary set should be closed to prevent any remaining fluid in the secondary bag from being delivered at the primary delivery rate.

Software version 5.02.03 and earlier

1. Make sure you have prepared the pump for a secondary infusion, using the steps in "Preparing the Pump for a Secondary Infusion" section, beginning on page 20.
2. Follow the steps for programming the primary bag infusion as described in either "Programming the Pump Using the Drug Error Prevention Mode" section, beginning on page 24 or "Programming the Pump Using the Basic Mode" section, beginning on page 28.
3. When you have finished programming the pump for the primary infusion and before you run the infusion, press **SETUP** to begin programming the secondary bag.
4. **If the drug is to be delievered using the DEP**, select the drug from the MDL:

   NOTE: The drug must be pharmacy/hospital-approved for delivery as a secondary line.

a. Using the keypad, type the drug's first two letters and press **OK**. All drugs beginning with those two letters will appear.

b. Use the arrow keys to scroll to the desired drug and press **OK**.

5. **If the drug is to be delivered using the Basic mode:**

   a. Press **BASIC**.

   b. Use the arrow softkeys to change the bag to secondary.

   c. Press **OK** and select mL/hr or dose rate mode.

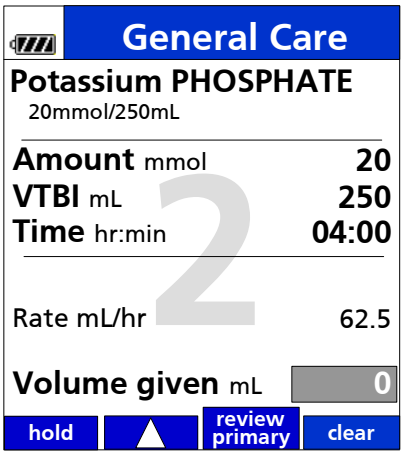
6. Confirm the values on the setup screen:

   a. Confirm the drug and concentrations are correct (if selected).

   b. Enter all required data, and press **OK** after each entry.

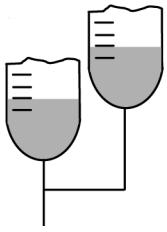
   c. To avoid infusing residual amounts of the secondary container at primary flow rates, be sure to properly set the secondary VTBI value. Secondary VTBI should equal secondary bag volume.

   NOTE: A "watermark" indicator is displayed behind the parameter data to help distinguish the Secondary (2) setup screen from the Primary (1) setup screen. This watermark does **not** appear on Primary-only infusions.



7. Press **RUN** to begin the secondary infusion.

   The "two bag" icon denotes the secondary is running.



8. Open the roller clamp for the secondary set when prompted. Press **OK** to confirm accomplishment of that step and begin delivery.

9. Check Flow confirmation is displayed. If the secondary rate is above 300 mL/hr, a dialog box appears prompting observation of the primary drip chamber.
   - If drops are seen, the primary line should be clamped closed. Press **YES** in this dialog box if a clamp is being applied to the primary line. Upon completion of the secondary infusion, the pump will enter a KVO state and it will ask for the removal of the clamp from the primary line. Press **OK** once the clamp has been removed to clear the alert and begin the primary delivery.
   - Press **NO** if drops are not flowing as indicated and follow the displayed instruction.
10. Upon completion of the secondary infusion, transition to the primary infusion shall be automatic and a "one bag" icon shall replace the "two bag" icon on the run screen.

NOTE: Upon completion of the secondary infusion, the clamp on the secondary set should be closed to prevent any remaining fluid in the secondary bag being delivered at the primary delivery rate.

Returning to the Primary Mode While Infusing in a Secondary Mode

This feature is only available when using software versions 6.01.00 and later.

1. Press **STOP.**
2. Press **CLEAR PROGRAM** softkey.
3. Press **SECNDRY** softkey.
4. Press **YES** softkey.
5. Close the clamp on the *secondary* line above the upper Y-site or remove secondary container and tubing.

CAUTION: Close the clamp on the secondary line or remove the Secondary container administration to prevent the secondary medication from flowing when the Primary mode is intended.

6. Press **OK** to continue.
7. The primary review screen appears.
8. Press **RUN** to start the primary infusion.
9. Check for flow and confirm that all clamps are open, there are no kinks in tubing, and drops are flowing. If everything is flowing properly, push the **YES** softkey.

Secondary Callback – Assigned to a Secondary Drug in the MDL

Secondary Callback is a feature that causes the pump to drop to the KVO Rate (1 mL/hr or the current infusion rate, whichever is less) at the completion of the Secondary Infusion and sound an audio alarm to call the clinician back.

If Secondary Callback is enabled* (per drug in the MDL) a dialog box shall be displayed at the completion of programming a Secondary infusion that asks if the clinician would like to be called back at the completion of the Secondary infusion. .

If YES is pressed, a “callback” icon will be displayed on the RUN screen during the secondary infusion to indicate that the callback feature is active.

If NO is pressed, the “callback” icon will not be displayed and the pump will automatically transition to the Primary infusion upon completion of the Secondary infusion.

*Version 6.2.2 MDL allows configuration as ON or OFF:

- If ON, the clinician will be presented with the Callback dialog upon completion of programming the Secondary infusion.
- If OFF, the pump will automatically transition to the Primary infusion upon completion of the Secondary infusion.
- Amount/Time infusions: Secondary callback operates in the same manner as for continuous secondary infusions with the addition of a “Line Flush” dialog box at secondary infusion complete.

*Version 6.5.4 MDL allows configuration as NEVER, OPTIONAL, or REQUIRED:

- If REQUIRED, the pump will not offer the clinician the Callback dialog and the pump will drop to the KVO Rate at the completion of the Secondary infusion and sound an audio alarm to call the clinician back.
- If OPTIONAL, the clinician will be presented with the Callback dialog upon completion of programming the Secondary infusion.
- If NEVER, the pump will automatically transition to the Primary infusion upon completion of the Secondary infusion.

Pump stops (KVO rate) and a callback alarm occurs when the secondary infusion completes.

1. Press **STOP** at completion (KVO).
2. Return to secondary setup or return to primary infusion.

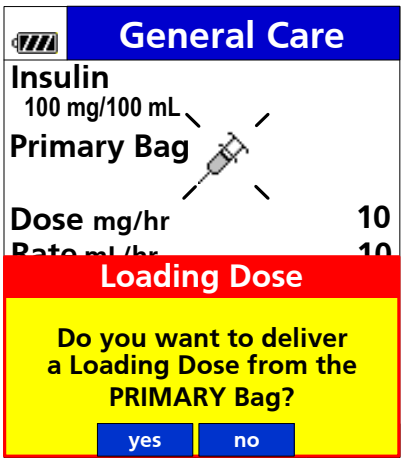
Programming a Loading Dose

This feature is only available when using software versions 6.01.00 and later.

When programming an infusion using the DEP mode, you can select a loading dose.

1. A loading dose is selected in the MDL (Master Drug Library) and infuses at the beginning of an infusion.
2. A loading dose amount, time and limits are assigned to drugs in the MDL.

3. A loading dose icon (syringe) is displayed next to the “Primary or Secondary Bag” line on a completed setup screen.
4. After all infusion values are entered, a loading dose dialog box displays:“Do you want to deliver a Loading Dose from the PRIMARY (or SECONDARY) bag? (**YES/NO**)



5. If you select **YES**, the loading dose setup screen displays.
6. Enter all required data, and press **OK** after each entry.
7. Press **RUN** to start the delivery of the loading dose.
8. Check for flow and confirm that all clamps are open, there are no kinks in tubing, and drops are flowing. If everything is flowing properly, push the **YES** softkey.

At the completion of the loading dose, transition to the primary infusion rate is automatic.

Programming a Bolus

This feature is only available when using software versions 6.01.00 and later.

A Bolus is a large IV dose of a drug given all at once at the start of treatment, which raises the concentration in the body to a therapeutic level.

- Can be delivered in Basic mode or in DEP Mode (through the Master Drug Library).
- Amount, time and limits are assigned to drugs in the MDL.
- Can be programmed while the pump is stopped or while infusing

To program a Bolus:

1. Press the **BOLUS** softkey. The bolus setup screen appears.
2. Enter all required data, and press **OK** after each entry.
3. Press **RUN** to start bolus delivery.

At the completion of the bolus, transition to the primary infusion rate is automatic.

Manual /Multi-Step Programming

The Manual (RAMP/Multi-Step) Programming Mode allows the pump to be programmed with up to 10 individual infusion steps using either the Drug Error Prevention or Basic Programming Operations. Drugs are eligible for use in the Manual Programming Mode, provided that the selected drug has not been specifically assigned to either the primary or secondary bag as identified in the pump's Master Drug Library. In software versions 6.04.01 and later "Primary Only, Multi-Step" in the MDL is also available for multi-step programming.

1. Press the **ON/OFF** button to turn the pump on.
2. If the prior setup needs to be erased, press **YES** soft key.
3. Use the arrow keys to select the care area (nursing area) and press **OK**.
4. **If the drug is to be delievered using the DEP**, select the drug from the MDL as described in "Programming the Pump Using the Drug Error Prevention Mode" section, beginning on page 24.
5. **If the drug is to be delivered using the Basic mode,** enter the Basic mode:
   - For version 5.02.03 and earlier, press **BASIC.**
   - For version 6.01.00 and later, type the lettters **BA**, select **Basic**, and press **OK**.
6. On the screen where you select the primary or secondary bag, press the **RAMP/MULT-STEP** softkey to enter the Manual Programming Mode.
   - **Ramp** softkey for software version 5.02.03 and earlier
   - **Multi-Step** softkey for software version 6.02.00 and later

   NOTE: The Manual Program Mode is not available for the secondary bag or the primary bag when a secondary program exists in memory.

   NOTE: If the selected drug has been configured in the MDL as a Primary Only Multi-step infusion, bag selection will be bypassed and the Manual Program Mode setup screen will be displayed.
7. In the Manual Programming Mode, continue with the setup as described in the Basic or Dose Error Prevention programming sections.

   A step indicator bar is located at the top of the screen. The bar shows which steps within the program have parameter data (a small white highlight) and which step is currently being viewed (a full white highlight).
8. When the setup of an individual step has been completed, press **OK** to advance and program the next step.

   When the 10th step has been programmed, the program schedule is complete and no more steps may be programmed.

   NOTE: Only one step is necessary to start a program however it must be the first and only programmed step. The pump may not be started if setup data is missing from any step in the program. Any parameter data missing within the program shall be identified in a popup message when a program attempts to start.

9. View the setup data for any programmed step by moving the highlight (using the up arrow softkey) to the step indicator bar located at the top of the setup screen and then using the left and right arrow softkeys to move from step to step.

   NOTE: A one-second delay exists from the time a step is selected and when its setup data is displayed. This delay is to allow rapid scrolling along the step bar without updating the screen contents repeatedly and unnecessarily.

   - If the pump is stopped, you can change any setup data by navigating to that step and pressing **OK** to move to the values that must be changed.
   - If the pump is running, you can view any programmed step by pressing the **REVIEW** softkey; however, no values can be changed with the exception of the Volume Given value, which can be cleared by pressing the **CLEAR** softkey.

10. Press **RUN** to start the program.

    The run screen appears as described in the mL/hr or Dose Error Prevention programming sections with the addition of a program step indicator. This indicator displays the current program step in the "Step x of y" format, where x is the current step being delivered and y is the total number of programmed steps.

11. Check the flow and confirm that all clamps are open, there are no kinks in tubing, and drops are flowing. If everything is flowing properly, push the **YES** softkey.

12. When the program completes, press the **STOP** key.

    The program schedule automatically resets itself and may be restarted without entering/reentering any setup data.

    NOTE: Always verify current program parameters for each step prior to starting a new infusion.

    The program will be retained indefinitely during power off cycles until reset. To reset the program press the **RESET** softkey from the program stopped screen.

Clearing the entire multi-step program

To clear the entire program, press the **CLEAR PROGRAM** softkey and answer **YES** to the confirmation screen.

Clearing an individual step

To clear the setup data from any individual step:

1. Make sure the pump is stopped.
2. Press the **REVIEW** softkey
3. Use the arrow softkeys to move the highlight to the desired step in the step bar.
4. Press the **CLR STEP** softkey.

   NOTE: Clearing a step does not delete that step unless it is the last step in the program.

Cyclic TPN Mode

This feature is only available when using software versions 6.02.00 and later.

The cyclic TPN mode is designed to deliver TPN in an automatic ramp up, main rate and taper down program. The infusion schedule is calculated with the rates and volumes for 10 ramp steps up occupying 10% of the total infusion time, 10 taper down steps occupying another 10% and the main rate accounting for the remaining 80% of the infusion time.

To program cyclic TPN:

1. Press the **ON/OFF** button to turn the pump on.
2. Use the arrow keys to select the care area (nursing area) and press **OK**.
3. Select **TPN** from the MDL.
4. Select cyclic **TPN** from the MDL.
5. Enter the program VTBI, and press **OK**.
6. Enter the program time, and press **OK**.
7. View display screen with main rate, VTBI, prog time, ramp up time, main step time,taper down time, and volume given mL.
8. Press **RUN** to start infusion.
9. Check the flow and confirm that all clamps are open, there are no kinks in tubing, and drops are flowing. If everything is flowing properly, push the **YES** softkey.
10. Observe mL remaining value and green infusing icon.
11. Press **REVIEW** softkey to display program status.
12. To begin early taper down, press **TAPER DOWN** softkey.
13. “Are you sure you want to begin the taper down?” displays on screen. Confirm by pressing the **YES** softkey.
14. At completion, the pump infuses at KVO. Press **STOP** to automatically reset the program from the beginning.

Once the TPN program starts delivery, no changes to the infusion parameters can be made.

Titrating

Software version 6.03.01 and later:

To titrate flow rates without stopping the pump:

1. Press the **TITRATE** softkey.
2. Observing the displayed soft rate limits, enter a new flow rate.
3. Press **OK**.

Software version 6.01.00 and later:

To titrate flow rates and VTBI without stopping the pump:

1. Press the **TITRATE** softkey.

2. To titrate dose, press **DOSE** softkey.
3. To titrate rate mL/hr, press **mL/hr** softkey.
4. Observing the displayed hard and soft dose or mL/hr flow rate limits, enter a new dose or mL/hr flow rate.
5. Press **OK**.

   If soft limits are exceeded, press **YES** to accept new value or **NO** to return to prior value.
6. To titrate VTBI, press **VTBI** softkey, enter new value, and press **OK**.

Software version 5.02.03 and earlier

To titrate flow rates without stopping the pump (not available in Program Modes):

1. Press the **TITRATE** softkey.

2. Observing the displayed hard and soft rate limits, enter a new flow rate.
3. Press either **RUN** or **OK**.

Delayed Start

This feature is only available when using software version 5.02.03 and earlier.

The start of any programmed infusion can be delayed by up to 12 hours.

1. On the infusion set up screen, enter any value between one minute and twelve hours (00:01 to 12:00, hr:min) on the delay time parameter and press **OK**.
2. Once a delay time is entered, the infusion programming is complete, and the set is loaded, press the **RUN** key to begin the infusion delay timer.

   The delay running screen appears with the remaining delay time shown in a flashing format.

When the delay time period expires, the pump begins delivery of the programmed infusion.

Stopping/Cancelling the Delay Timer

While the delay is running it may be stopped or cancelled.

- **To stop the delay**, press the **STOP** key. The display updates to DELAY STOPPED and the delay timer is paused and no longer flashes.
- **To cancel the delay**, press the **CANCEL** softkey. The remaining delay time is cleared and the display updates to PUMP STOPPED).

Changing the Delay Timer

The remaining delay time value may be changed while the delay is running or stopped.

1. Press **REVIEW/PROGRAM** softkey to display the setup screen.
2. Move the cursor to the Delay value and enter the new desired delay time and press **OK**.

NOTE: The new delay time is immediately applied. The Delay time value may not be cleared while the delay is running.

Values Differ

This feature is only available when using software version 6.04.01 and later.

Blind weight reentry display (set up in the Master Drug Library) indicating the weight or BSA entered does not match the weight or BSA initially entered on the set up programming screen.

PUMP OPERATION

Operating Tips

Follow all prompts on the pump screen.

- Always press **OK** to confirm entries and changes.
- Follow all prompts on screen to clear alarms.

Be sure to load sets properly.

- Start with a fresh section of tubing loaded in the pump, make sure there is enough tubing for patient movement.
- To open the pump door, insert the gravity IV set's slide clamp fully into the keyhole.
- Load tubing tautly, from top to bottom in loading points 1, 2, 3 and 4, following the red/green prompts.
- Close the door with thumb pressure over both door hooks, which is at the top of the door and the bottom of the door.
- Open the slide clamp by pulling it straight up, while holding the tubing around it down.

Use the Drug Error Prevention (DEP) system.

- DEP system protects against human errors that could cause Adverse Drug Events.
- BASIC mode can not detect human errors.

Do not drop the power supply.

- The power supply is an electronic device. It is not simply a plug, and it will break if repeatedly dropped.
- Keep the power cord plugged in whenever the pump is not in use.

Follow secondary procedures.

- Use drop hooks to drop primary containers below secondary containers.
- With secondary rates above 300 mL/hr, look for and clamp off primary line siphoning.

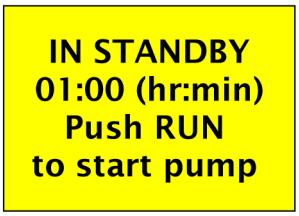
Placing the Pump on Standby (Hold Mode)

You can place the pump in a standby state to prevent the occurrence of the Inactivity Alarm (see "Alarms" section, beginning on page 46) for the period of time specified in the User Settings / Alarm Settings menu option. The default setting is to provide an infinite period of time; however, this value may be changed from one minute up to 99 hours and 59 minutes.

1. Load the set and complete the infusion setup.

   Once setup has been completed and the highlight is on the Volume Given mL value, a display appears stating that the pump may either be started or it may be placed in standby mode.

2. To place the pump in standby, press the **HOLD** softkey.

   When standby is activated, the In Standby message is displayed in a flashing format.

   NOTE: If the delay period is set to infinite, the time value in the display will be replaced with a dashed line.

3. While in standby, press **RUN** at any time to begin the infusion. Pressing any other key or opening the pump door cancels standby mode.

Standby in non-alarm condition

Pump Standby may also be used when the pump is stopped in a non-alarm condition. Press the **REVIEW/PROGRAM** softkey and then press the **HOLD** softkey from the setup screen.

Patency Checks

To confirm the IV line is not blocked:

1. Press **STOP**.
2. Open the door.
3. Troubleshoot a down stream pressure occlusion based on your facility's policy.

Operating the Keypad Lock

The keypad can be locked in two ways:

- Manually - by entering the keypad lock code
- Automatically - by activating the Auto Keypad Lock feature in the MDL.

Manually locking the keypad

To lock the keypad, enter the code 429 (“K”, “E”, “Y”).

NOTE: 429 is the default keypad lock code. Refer to the Library Configurations section in the MDL User Manual (P/N 41020) to change the keypad lock code.

This code is entered when the pump is in the run mode to prevent unauthorized activation of specific key entries. A popup message appears briefly indicating the keypad has been locked. The Key lock icon is shown on the top left corner of the screen.

When the keypad is locked, you can press the **REVIEW** softkey to view infusion setup data. However, no values can be changed and therefore navigation from value to value is not allowed when the keypad is locked.

The keypad allows certain alarm conditions to be silenced and cleared while in the Keypad Lock mode.

The code must be re-entered to unlock the keypad. If the keypad is unlocked while reviewing the setup data and the pump is not stopped, the keypad will automatically relock upon return to the run screen.

Automatically locking the keypad

In the MDL, you can set the keypad to lock automatically by activating the Auto Keypad Lock feature by care area.

Keypad lock code is set hospital wide and may be 1 to 4 digits (1-9 only, zero can not be used).

Keypad will be automatically locked 60 seconds after the run key is pressed.

Passcode must be entered on the keypad to unlock.

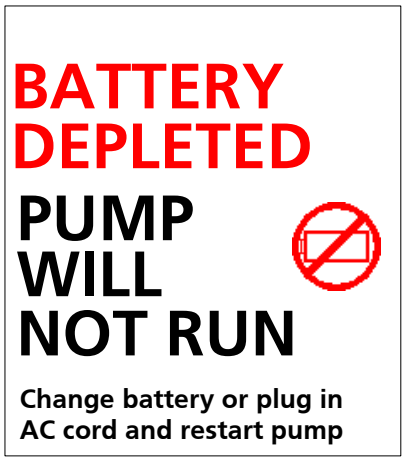
Always guard the keypad lock code from unauthorized view or access. Uncontrolled access by a patient or family member may cause injury to the patient.

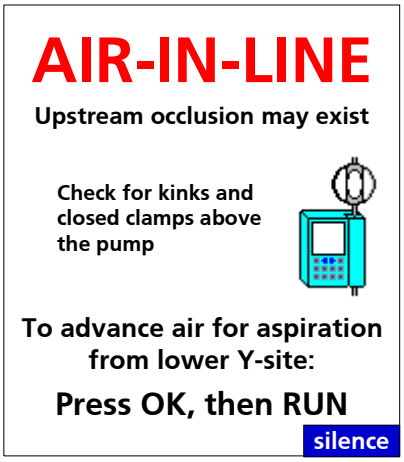
For more iformation about this feature, refer to the Care Area Configurations section in the MDL User Manual (P/N 41020).

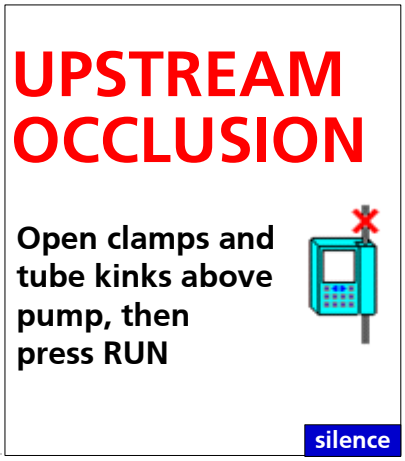
ALARMS

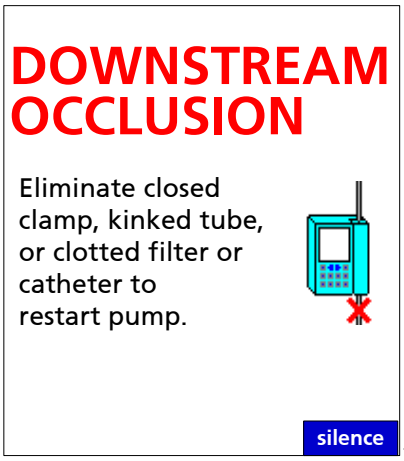
The Spectrum Pump has a number of alarms that appear when specific conditions exist. These alarms are annunciated with a tone and an alarm message is displayed on the pump screen. The message states the reason for the alarm and contains prompts for clearing the alarm.

Figure 13. Example Alarms Messages




AIR-IN-LINE
Upstream occlusion may exist
Check for kinks and closed clamps above the pump
To advance air for aspiration from lower Y-site:
Press OK, then RUN
silence





Silencing an Alarm

To silence the audio tone for an alarm, press the **SILENCE** softkey or any key on the keypad. This stops the tone from annunciating for 2 minutes. If the alarm has not been cleared after 2 minutes, the alarm tone will resume.

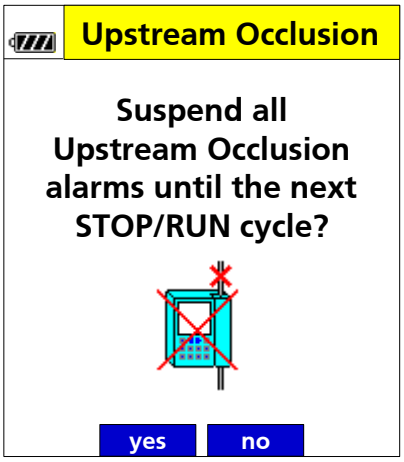
Clearing an Alarm

To clear an alarm, follow all of the prompts and instructions in the alarm message. The alarm clears after you have corrected the alarm condition and followed all of the prompts.

Alarm Messages

Alarm	Action
Air-in-Line	Check for kinks or closed clamps above the pump that may result in an upstream occlusion. Evaluate tubing for presence of air. Press **OK** and then press **RUN** to advance small bubbles past the air detector. Each press of **RUN** advances approximately 0.1 mL. Use a syringe to aspirate air from the lower Y site or re-prime the set.
Audio	May be silenced for 2 minutes by depressing any key. Low, medium and high volume levels may be selected in the User Options, Alarm Settingsscreen.
Battery Missing	Battery not detected. Check to make sure it is fully latched.
Depleted Battery	The battery is fully depleted and unable to run the pump. To continue the infusion and recharge the battery, plug the pump's AC power adaptor into an AC outlet. Confirm that the adaptor's power cord connector is attached to the pump.
Door Not Fully Closed / Set Outside Channel	The pump's door has not closed and latched correctly. Ensure the slide clamp is closed, open the door using the slide clamp and re-load the IV set. Close the pump's door ensuring both door latches shut securely.
Door Open	The slide clamp has been closed and inserted in the keyhole when the pump was running. The pump is stopped. Close the door, open the slide clamp, remove it from the keyhole and press **RUN** to restart the infusion OR open the door and unload the IV set.

Alarm	Action
Downstream Occlusion	Eliminate a closed clamp, kinked tube, positional catheter, clotted catheter, clogged IV filter or other sources of occlusion below the pump.
Downstream Pressure Limit – Reset Setting	The downstream pressure limit differs from care area default (set in Master Drug Library). Select **YES** to reset or **NO** to keep the current setting.
Inactivity Alarm	The pump has been inactive for 2 minutes and no action has been taken. Follow the prompted action and resume or restart the pump by pressing **RUN**.
Infusion Complete	The VTBI (volume to be infused) has counted down to zero and has been delivered. The pump is running at a rate of 1.0mL/hr (KVO rate) – keep vein open (or the actual infusion rate, whichever is lower). Press **STOP** to halt the KVO rate and return to the setup screen. Select a new VTBI value and press **RUN**.
In Stop – Slide Clamp Closed	Open slide clamp and push **RUN** (or unload set).
Line Flush Complete	The line flush VTBI has counted down to zero mL. the pupmp is running at a KVO rate of 1 mL/hr. Press **STOP** to halt the KVO rate and return to flush prompt. (Maximum 3 line flushes are allowed). This alarm applies to software versions 6.03.01 and later infusing a primary or secondary drug in amount/time modes only.
Low Battery	The low battery alarm threshold has been reached. Plug the AC Power Adaptor into the pump and into the AC source outlet as soon as possible to recharge the battery.
Slide Clamp Closed	Open slide clamp and press **RUN** or reload the set.
System Error	An internal fault has been detected. Some faults can be cleared by either cycling power (off, then on) or by turning the power off, disconnecting the battery, reconnecting it several seconds later and pressing the **ON** key. If neither procedure clears the fault, return the pump for service.
Upstream Occlusion	Eliminate the occlusion by checking for an upstream closed clamp, kinked tube or closed burette valve and press the **RUN** key.

Alarm	Action
Upstream Occlusion Suspension	If a drug has been checked as an Effervescent Drug in the MDL (Drug Configurations / Upstream Occlusion Alarm), once flow has been confirmed (check flow display), if the operator considers the occlusion alarm to be a nuisance, they may choose to suspend the alarm until the next **STOP** key press.  After **YES** is pressed to check flow, the operator may select to suspend the upstream occlusion alarm temporarily on the Occlusion Alarm screen. If **YES** is selected, the upstream occlusion alarm "OFF" icon displays on the **RUN** screen. With the next **STOP** key press, or after the door is opened, the alarm will again become enabled. This alarm applies to operating software versions 6.03.01 and later.
Very Low Battery	Less than ½ of the low battery capacity remains. The AC Power Adaptor should be plugged in immediately. The tutorial to check the AC Power Adaptor will automatically begin (see "APPENDIX F - Low / Very Low Battery Tutorial" section, beginning on page 89).

Preventing Nuisance Alarms

Check the following items to prevent nuisance alarms:

- Remove all air from IV sets and Y sites.
- Do not administer extremely cold or hot solutions. Warm solutions to room temperature before use to help prevent nuisance upstream occlusion or air-in-line alarms caused by out-gassing of micro bubbles.

- Do not use effervescent, foamy or frothy solutions.
- Invert (do not shake) IV bags that need to be mixed.
- Fill drip chambers half way.
- Do not load pumped on IV set tubing in the pumping channel or in the air and occlusion detector areas.
- Follow prompts and HELP (operating software 6.02.00 and earlier) screens.
- Use only compatible IV sets as labeled and identified on the SIGMA pump.
- Keep the tubing channel clean and dry.
- Avoid empty IV containers by properly setting VTBI values.
- Plugin pump's AC power adaptor to maintain battery charge.
- Using the Low Downstream pressure setting at flow rate setting above 500 mL/Hr may cause Downstream nuisance alarms that are created by IV set pulsation.

Managing Bolus before Occlusion (Downstream) Release

Managing unintended small bolus releases when clearing downstream occlusions

When a downstream occlusion alarm occurs, pressure and a small volume of <0.98 mL of fluid (the "bolus") builds up between the pump and the point of occlusion. When it might be harmful to infuse the bolus into the patient, simultaneously withdraw 0.9 mL of fluid from the lower "Y" site of the IV set and eliminate the source of the occlusion.

Battery Warning Levels

The pump provides three warning levels as the battery capacity decreases while operating on battery power. These levels are:

- Low Battery
- Very Low Battery
- Battery Depleted

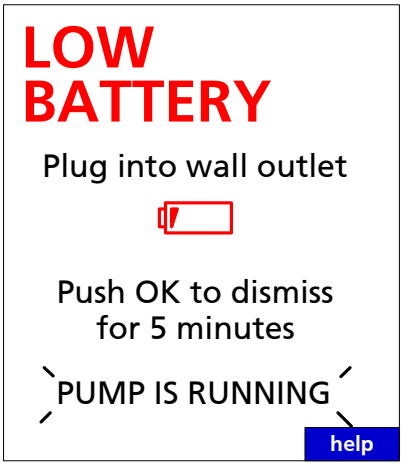
There is ample time between the alarms for the pump to be plugged into main power. The trouble-shooting tutorial also automatically pops up on the pump screen to guide the user through the process. See "APPENDIX F - Low / Very Low Battery Tutorial" section, beginning on page 89.

If the pump is not plugged in, the battery continues to slowly discharge even if the pump is turned off.

Low Battery

When the battery is low, the pump sounds a triple-beep audio alarm every 5 seconds. Press **OK** to temporarily suspend this alarm.

Figure 14. Low Battery Alarm



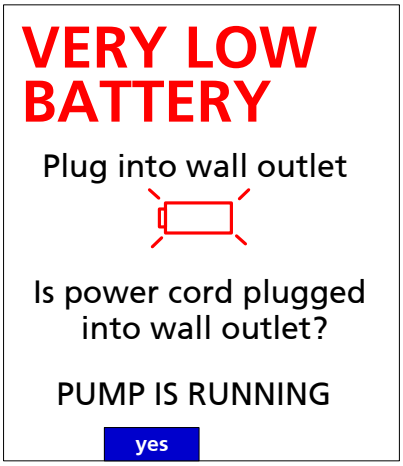
If the pump is not plugged in or the alarm is not acknowledged after 2 minutes, the alarm volume increases and the troubleshooting tutorial automatically begins.

When the Low Battery warning initiates, a minimum of 30 minutes of runtime remains.

Very Low Battery

If the battery level drops below the low-battery level, the message changes to Very Low Battery and begins to flash. The back light also dims to reduce battery usage.

Figure 15. Very Low Battery Alarm



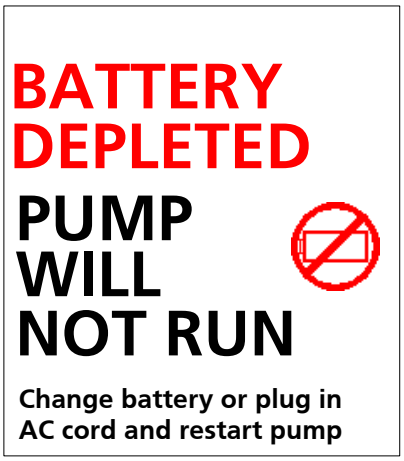
The troubleshooting tutorial starts automatically.

When the Very Low Battery warning initiates, a minimum of 15 minutes of runtime remains.

Battery Depleted

If the battery level drops below the Very Low Battery level, the message changes to Battery Depleted.

Figure 16. Battery Depleted Alarm



The pump will stop running. If the pump is not plugged in within 3 minutes, the pump will shut itself off.

CLEANING AND STORAGE

The SIGMA Spectrum should be cleaned and disinfected for each patient use according to facility protocol.

Compatible Cleaners

Refer to DOC 11318 for complete listing

- 10% solution of bleach and water
- Up to 90% Isopropyl alcohol
- Caltech Industries Dispatch®
- Steris TBQ® and Steris Germicidal Surface Wipes, Product Number 1608-GS
- Metrex Cavicide® and Cavi Wipes™
- Contact SIGMA for additional information

Cleaning the Pump

To clean the pump:

1. Turn the pump off and unplug the AC power adaptor from the power source.
2. Place the pump in an upright position.
3. Apply the compatible cleaning agent with a dampened cloth per the manufacturers' instructions using appropriate dilution ratio.

   Disinfectants should remain on the pump's surface in an even, but not dripping, film for the recommended contact time for the compatible cleaning agents.
4. Open the pump's door using a standard IV set's slide clamp.
5. Clean the speaker vent, power adaptor connector, door release, keyhole and pumping channel areas with soft swabs.
6. Apply solutions sparingly to the swabs and wipe down the necessary areas.

   Do not use rigid cleaning instruments or spray solutions directly on the pump and its accessories.

   NOTE: For severe solution spills it is recommended that the Standard Battery/ Wireless Battery Module be removed. The Battery Pack cavity area of the pump may be cleaned by wiping down those regions with a dampened cloth as described previously.
7. Dispose of all cleaning materials (including the slide clamp) as required per facility protocol/biohazard policy.

CAUTION:

- Alcohols are flammable and should not be used for Standard Battery/Wireless Battery Module cleaning/disinfection. Always use alcohols in a well-ventilated area.
- When cleaning the Standard Battery/Wireless Battery Module, care should be taken to prevent shorting of the pack's exposed terminals.
- Do not sterilize this device by autoclaving or ETO gas.
- Do not immerse any part of this device or allow cleaning fluids to seep inside the pump.
- Do not use phenol-based cleaners/disinfectants. Phenols degrade plastics and membrane switches. Phenols are intended for cleaning of hard non-porous surfaces such as: sinks, counter tops, and stainless steel.
- Do not use abrasive cleaners.

Storing the Pump

- Connect the AC power adaptor to the pump and supply source power to charge the pump's battery during storage. This insures a fully charged battery for subsequent use.
- Do not store or transport pumps in ways that might result in physical damage.
- For extended periods of storage remove the battery and repackage the pump in the original shipping container.
- Storage at elevated temperatures will diminish battery life.
- Refer to Specifications section of this manual for recommended storage temperature and humidity.

Servicing the Pump

CAUTION: Electric shock hazard.

Refer servicing to SIGMA trained and qualified service personnel. Refer to the Service Manual for inspection and maintenance procedures.

COMPATIBLE IV SETS

SIGMA Nitroglycerin/Lipid Sets

Connect IV containers to catheters.

Set description:

Cat No. 99021	Pump Calibration Hospira	Length: 99” overall 15” PVC pumping section DEHP free vented drip chamber (60 drops/mL) Polyethylene lined tubing Priming Volume: 20mL Luer Lock

Figure 17. Nitroglycerin/Lipid Set

SIGMA Y-Type Blood Sets

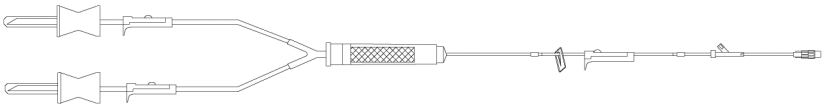
Connect Blood and Saline Bags to catheters.

Set description:

Cat No. 99031	Pump Calibration Hospira	Length: 104” overall 15” PVC pumping section 200 Micron blood filter Lower Y injection site Priming Volume: 42mL Luer Lock

NOTE: IV Sets are Latex Free

Figure 18. Y-Type Blood Set



Compatible Hospira IV Sets

The following is a partial listing of the Hospira IV sets compatible with the SIGMA Spectrum pumps that have been calibrated for use with Hospira nominal size 0.100" I.D. Series IV set tubing. Please consult DOC 11181 for a full listing of compatible sets.

Sets must include a Green Slide Clamp or a Yellow Keyed Slide Clamp on the section of the set to be placed into the Spectrum pump.

or

No.	Brief Description
Primary Set Macro (15 Drops/mL)	
11309-58	LS Primary Piggyback Set, PP backckeck valve, 2 PP Y-Sites, & OL[2, 6, 7], 106”
11540-58	LS Primary Piggyback Set, PP backcheck valve, PP Y-site & OL2, 80”
11545-58	LS Primary Set, PP Y-site & OL, 78”
11679-65	LS Primary Piggyback Set with inline backcheck valve, 2 PP Y-sites, and OL[2], 100”
11960-68	LS Convertible Pin I.V. Set, CLAVE Y-site and OL, 100”
11961-68	LS Primary Piggyback Set with inline backcheck valve, 2 CLAVE Y-sites & OL[2], 100”
11965-68	LS Primary Piggyback Set, inline backcheck valve, 3 CLAVE Y-sites, and OL[2], 7, 100”
12574-48	LS Primary Set, Convertible Pin & OL, 100”
20778-48	LS Primary Set with backcheck valve, Yellow Key Slide Clamp, 2 CLAVE Y-Sites, & OL[2, 5], 100”
20793-48	LS Primary Set, Yellow Key Slide Clamp, with inline backcheck valve, 3 CLAVE Y-sites, 0.2 micron filter, & OL2, 3, 5, 6, 120”
20794-48	LS Primary Set , Yellow Key Slide Clamp, with inline backcheck valve, 3 CLAVE Y-sites, & OL[2, 5, 6, 120”
20795-48	LS Primary Set , Yellow Key Slide Clamp, with inline backcheck valve, 3 CLAVE Y-sites, & OL[2, 5, 120”, w/Extension
20803-48	LS Primary Set, Yellow Key Slide Clamp, CLAVE Y-site & OL[5], 100”
20815-48	LS Primary Set, Yellow Key Slide Clamp, with inline backckeck valve, 3 PP Y-Sites, & OL[2, 5, 110”
Primary Set Micro (60 Drops/mL)	
11411-78	LS MIcrodrip Primary Piggyback Set, w/ backckeck valve, 2 PP Y-Sites, & OL[1, 2, 6, 7,100”
11539-78	LS Microdrip Primary Set, PP Y-site & OL[1], 70”
11550-78	LS Microdrip Primary Piggyback Set, PP backcheck valve, PP Y-site Set OL[1, 2, 80”
11962-78	LS Microdrip Piggyback Set, with inline backcheck valve, 2 CLAVE Y-sites & OL[1, 2, 100”
12058-78	Microdrip Set with yellow striped tubing, CAIR Clamp & OL[1], 112”
12426-48	LS Microdrip Piggyback Set with inline backcheck valve, 3 CLAVE Y-sites & OL[1, 2, 7], 100”

12453-48 LS Microdrip Primary Set, 1 CLAVE Y-site & OL[1], 100”

20779-48 LS Microdrip Primary Set with backcheck valve, Yellow Key Slide Clamp, 2 CLAVE Y-Sites, & OL[1, 2, 5], 100”

Primary Filter Set Micro (60 Drops/mL)

20801-48 LS Primary Microdrip Filter Set with backcheck valve, Yellow Key Slide Clamp, 2 CLAVE Y-Sites, & OL[1, 2, 3, 5,] 100”

Primary Filter Set Macro (15 Drops/mL)

11538-68 LS Primary Piggyback Set, 0.2 micron filter, PP backcheck valve, PP Y-site & OL[2, 3,] 80”

11963-68 LS Primary Piggyback Set, with inline backcheck valve, 2 CLAVE Y-sites, 0.2 Micron High Pressure Filter & OL[2, 3, 7,] 100”

12573-48 LS Primary Set, 0.2 micron filter, specific pumping section, 1 CLAVE Y-Site & OL[3, 6, 7,] 110”

20780-48 LS Primary Set, 0.2 micron filter with backcheck valve, Yellow Key Slide Clamp, 2 CLAVE Y-Sites, & OL[2, 3, 5,] 100”

150 mL Burette Set Macro (15 Drops/mL)

12907-65 LS Burette Set, backcheck valve, 2 PP Y-Sites, 1 CLAVE Port, & OL[2, 4, 7, 8,] 106.5”

20797-48 LS Burette Set, Yellow Key Slide Clamp, 3 CLAVE Ports, & OL[4, 5, 6,] 120”

20798-01 LS Burette Set, Yellow Key Slide Clamp, 4 CLAVE Ports, & OL[4, 5,] 167”, w/Extension

150 mL Burette Set Micro (60 Drop/mL)

11398-20 LS Microdrip Filter SoluSet 150 x 60, PP site on burette, capped port, PP Y-Site & OL[1, 4, 7,] 100”

11964-02 LS Filter SoluSet 150 x 60, slide clamp, 1 CLAVE Y-Site & OL[1, 4, 7, 8,] 77”

12341-01 LS Microdrip SoluSet 150 x 60, capped port, 1 CLAVE Y-Site & OL[1, 4, 7,] 77”

20804-01 LS Microdrip Burette Set, Yellow Key Slide Clamp, Filter Valve, Capped port, 1 CLAVE Y-Site & OL[1, 3, 4, 5, 7,] 110”

Primary Nitroglycerin Set Macro (15 Drops/mL)

11993-78 Nitroglycerin Primary Pump Set (not for gravity administration), specific pumping section with slide clamp 6, 110”

Fat Emulsion Set Macro (15 Drops/mL)

12060-58 Fat Emulsion Set, non-DEHP (except pump segment with connections), slide clamp on pump segment 6, 110”

Y-Type Blood Set (10 drops/mL)

11994-48 Y-Type Blood Set, 170 micron blood filter chamber, & OL[3,9,] 105”

12450-48 LS HEMA Y-Type Blood Set, 1 CLAVE Y-Site, w/210 micron blood filter chamber, & Secure Lock3, 9, 100”

20796-48 LS Y-Type Blood Set, Yellow Key Slide Clamp, 1 CLAVE Y-Site, w/170 micron filter, & OL[3, 5, 9,] 110”

20805-48 LS Y-Type Blood Set, Yellow Key Slide Clamp, 1 CLAVE Y-Site, w/210 micron filter, & OL[3, 5, 9,] 100”

20806-48 LS Y-Type Blood Set, Yellow Key Slide Clamp, 1 CLAVE Y-Site, w/170 micron filter, & OL[3, 5, 9,] 100”

All sets use roller clamps referenced to as CAIR® clamp. All sets (except the Blood sets) use convertible pins.

LS = LifeShield®, OL = Option-Lok®, PP= Prepierced, CAIR®, CLAVE®, Option-Lok®, LifeShield®, Microdrip® SoluSet® are all registered names / trademarks associated with Hospira (Abbott Laboratories).

Compatible Hospira IV Sets – WARNINGS

The numbers reference the description listing table.

WARNING:

1. Microdrip chambers should not be used for flow rate settings greater than 200 mL/hr. Doing so may influence flow rate accuracy and cause nuisance air or upstream occlusion alarms.

2. When using sets with backcheck valves, flow rate settings should not exceed 500 mL/hr. Doing so may influence flow rate accuracy or cause nuisance upstream air or upstream occlusion alarms. Flow rates above 300 mL/hr may cause fluid to be siphoned from the primary container during piggyback operation (see Secondary Infusion).

3. Partially occluded filters can cause nuisance upstream air, upstream occlusion or downstream alarms and influence flow rate accuracy.

4. Burettes with closed vents, or shutoff valves will cause upstream occlusions that may not be detected by the infusion pump.

5. Yellow Key Slide Clamp sets are only compatible with Spectrum software versions 4.02.06 or higher. Keyed for correct direction of flow.

6. Sets having a length that is greater than 48 inches from the exit of the pump to the patient connection end may have an increased downstream occlusion pressure, time to occlusion and bolus at occlusion release. For rates of less than 100 mL/hr, the pump should be set to the LOW downstream pressure setting.

7. Some IV sets contain two or more slide clamps. Only the slide clamp on the pumping section or on the section with the main roller clamp should be used for pumping operation and clamp detection. Other slide clamps associated with the set need to be observed and controlled by the user.

8. This set is configured with a roller clamp above the set slide clamp. When loading it into the Spectrum pump ensure proper set orientation with slide clamp located above the pump.

9. Blood sets with both clamps closed above the blood filter will cause upstream occlusions conditions that may not be detected by the pump.

See the Specification Section for Downstream Occlusion times and bolus release information.

Compatible Baxter IV Sets

The following is a partial listing of the Baxter IV Sets compatible with the SIGMA Model Spectrum pumps that have been calibrated for Baxter "S" I.V. set tubing. Please consult DOC 11182 for a full listing of compatible sets.

All sets must include a Blue Slide Clamp on the section of the set to be placed into the Spectrum pump.

No.	Brief Description
Primary Set Macro (10 drops/mL)	
1C8109s	Solution Set, Male luer lock, 101"
1C8160s	Solution Set, Male luer lock, 69"
1C8296s	Solution Set, Male luer lock, 125"
2C6401s	Solution Set, Interlink Y-Site (1 ea) with luer lock adapter, lever lock cannula, 76"
2C6419s	Solution Set, Interlink Y-Site (1 ea) with luer lock adapter, DUO-VENT spike, 92"
2C8401s	Solution Set, Clearlink Y-Site (1 ea) with male luer lock, 76"
2C8419s	Solution Set, Clearlink Y-Site (1 ea) with male luer lock adapter, DUO-VENT spike, 92"
2C6519s	CONTINU-FLO Solution Set, Interlink Y-Site (2 ea) with luer lock adapter, backcheck valve[2], 89"
2C6537s	CONTINU-FLO Solution Set, Interlink Y-Site (3 ea) with luer lock adapter, backcheck valve[2], 110"
2C8515s	CONTINU-FLO Solution Set, Clearlink Y-Site (1 ea) with male luer lock, backcheck valve[2], 106"
2C8519s	CONTINU-FLO Solution Set, Clearlink Y-Site (2 ea) with male luer lock, backcheck valve[2], 112"
2C8537s	CONTINU-FLO Solution Set, Clearlink Y-Site (3 ea) with male luer lock, backcheck valve[2], 110"
3C0062s	CONTINU-FLO Solution Set, Interlink Y-Site (4 ea) with 4-way large bore stopcock extension set, backckeck valve[2, 7,] 123"
Primary Set Minidrip (60 drops/mL)	
2C6402s	Solution Set, Interlink Y-Site (1 ea) with luer lock adapter, lever lock cannula[1], 76"
2C6424s	Solution Set, Interlink Y-Site (2 ea) with luer lock adapter[1], 93"
2C8402s	Solution Set, Clearlink Y-Site (1 ea) with male luer lock[1], 76"
2C6520s	CONTINU-FLO Solution Set, Interlink Y-Site (2 ea) with luer lock adapter, backcheck valve[1, 2,] 89"
2C6546s	CONTINU-FLO SOLUTION SET, INTERLINK Y-SITE (3 EA) WITH LUER LOCK ADAPTER, BACK-CHECK VALVE[1, 2, 7,] 106"
2C8546s	CONTINU-FLO SOLUTION SET, CLEARLINK Y-SITE (3 EA) WITH MALE LUER LOCK, BACKCHECK VALVE[1, 2, 7,] 106"

PRIMARY FILTER SET MACRO (10 DROPS/mL)

2C6571s	CONTINU-FLO SOLUTION SET, 0.22 MICRON FILTER, INTERLINK Y-SITE (2 EA) WITH LUER LOCK ADAPTER, BACKCHECK VALVE[2, 3,] 105”
2C8571s	CONTINU-FLO SOLUTION SET, 0.22 MICRON FILTER, CLEARLINK Y-SITE (2 EA) WITH LUER LOCK ADAPTER, BACKCHECK VALVE[2, 3,] 105”

PRIMARY FILTER SET MINIDRIP (60 DROPS/mL)

2C6572s	CONTINU-FLO SOLUTION SET, 0.22 MICRON FILTER, INTERLINK Y-SITE (2 EA) WITH LUER LOCK ADAPTER, BACKCHECK VALVE[1, 2, 3,] 105”

BURETROL MINIDRIP (60 DROPS/mL)

2C7519s	150 ML BURETTE, INTERLINK Y-SITE (2 EA) WITH LUER LOCK ADAPTER, BALL VALVE DRIP CHAMBER[1, 4, 5,] 117”
2C7562s	150 ML BURETTE, INTERLINK Y-SITE (3 EA) WITH VALVELESS BURETTE[1, 4, 7,] 115”
2C7564s	150 ML BURETTE, INTERLINK Y-SITE (2 EA) WITH DRIP CHAMBER FILTER VALVE, MALE LUER LOCK ADAPTER[1, 4, 5, 7,] 105”
2C8819s	150 ML BURETTE, CLEARLINK Y-SITE (2 EA) WITH LUER LOCK ADAPTER, BALL VALVE DRIP CHAMBER[1, 4, 5,] 117”

Y-TYPE BLOOD SET (10 DROPS/mL)

2C6750Hs	BLOOD / SOLUTION SET, INTERLINK Y-SITE (1 EA) WITH LUER LOCK ADAPTER, (170 TO 260) MICRON FILTER3, 115”
2C8750s	BLOOD/SOLUTION SET, CLEARLINK Y-SITE (1EA) WITH LUER LOCK ADAPTER[3, 8] 112”

NITROGLYCERIN SET (10 DROP/mL)

1C8043s	VENTED NITROGLYCERIN SET WITH LUER LOCK ADAPTER, 12” PVC PUMPING SEGMENT 6, 133”

NITROGLYCERIN SET (60 DROP/mL)

2C7551s	VENTED NITROGLYCERIN SET, INTERLINK Y-SITE (1 EA) WITH LUER LOCK ADAPTER, 12” PVC PUMPING SEGMENT[1, 6,] 106”
2C8851s	Vented Nitroglycerin Set, Clearlink Y-Site (1ea) with luer lock adapter, 11” PVC pumping segment[1,6,] 105”

Buretrol, Clearlink, CONTINU-FLOW, and Interlink are all registered names / trademarks associated with Baxter International Inc.

Compatible Baxter IV Sets – WARNINGS

The numbers reference the description listing table.

WARNING:

1. Minidrip chambers should not be used for flow rate settings greater than 200 mL/hr. Doing so may influence flow rate accuracy and cause nuisance upstream air or upstream occlusion alarms.

2. When using sets with backcheck valves flow rate settings should not exceed 500 mL/hr. Doing so may influence flow rate accuracy or cause nuisance upstream air or upstream occlusion alarms. Flow rates above 300 mL/hr may cause fluid to be siphoned from the primary container during piggyback operation.

3. Partially occluded filters can cause nuisance upstream air, upstream occlusion or downstream alarms and influence flow rate accuracy.

4. Burettes with closed vents, or shutoff valves will cause upstream occlusions that may not be detected by the infusion pump.

5. Ball Valve operation may not be detected as an alarm condition when using the SIGMA Spectrum Pump.

6. Rigid polyethylene lined tubing, as is often used in nitroglycerine sets, may produce as much as 10 PSI downstream occlusion pressure above the lower limit of the SIGMA Spectrum Pump specification.

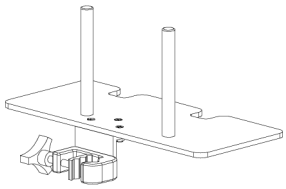
7. Some Sets contain two or more slide clamps. Only the slide clamp on the pumping section or on the section with the main roller clamp should be used for pumping operation and clamp detection. Other slide clamps associated with the set need to be observed and controlled by the user.

8. Blood sets with both clamps closed above the blood filter will cause upstream occlusions conditions that may not be detected by the pump.

See the Specification Section for Downstream Occlusion times and bolus release information.

ACCESSORIES

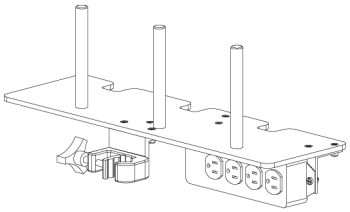
Tandem Carrier



Cat No. 55092NS

- Holds 2 Spectrum pumps
- Stainless upright tubes and aluminum plate
- C-clamp jaw opening expands to 1.5”
- C-clamp knob comes off if semi-permanent attachment of carrier is desired

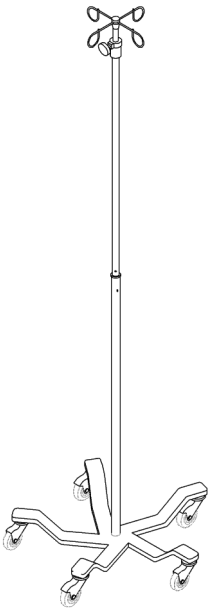
3 Pump Carriers



Cat No. 55093

- Holds 3 pumps.
- Stainless upright tubes and aluminum plate
- UL, CSA four outlet power strip for multi pole plug in (1 cord from IV pole to wall outlet)
- C-clamp jaw opening expands to 1.5”
- C-clamp knob comes off if semi-permanent attachment of carrier is desired

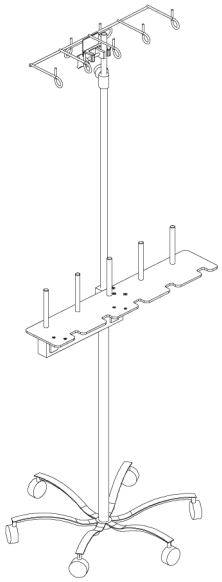
Single-Pole



Cat No. 55096

- Adjustable height stainless steel pole
- Revolving 4-hook top
- Stable 5-leg base with 3” casters

Multi-Pole

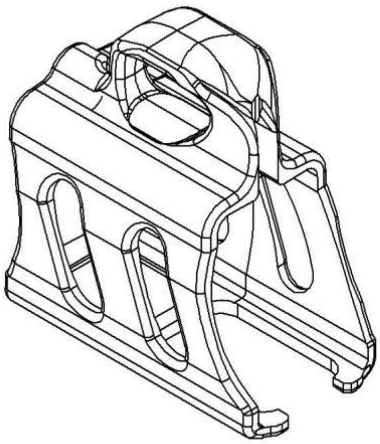


Cat No. 55088-1

- Holds 5 pumps
- Adjustable height stainless steel pole
- 7-hook top
- UL, CSA six outlet power strip for multi-pole plug in (1 cord from IV pole to wall outlet)
- Heavy-duty 6-leg base with 3” soft rubber casters
- Patient support ring attached to rear of plate

CAUTION: Securely mount IV pumps to pole by turning the mounting knob clockwise. To maintain IV pole stability never exceed 210 cm (83”) from floor to IV pole top, and limit bag volume at this extended height to < 1 liter (1000 cc).

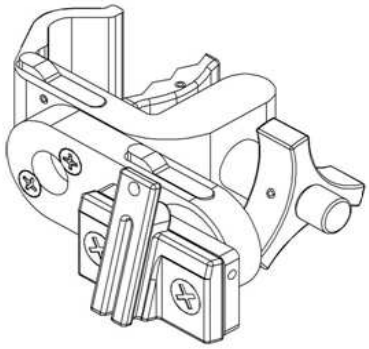
A.C. Power Adaptor Protector



SIGMA Part Number (P/N) 45742

- Snaps on the adaptor side of A.C. Power Adaptor
- Handle on the Protector helps for easy insertion and removal of adaptor (power supply) from receptacle
- Protects adaptor from damage

CAUTION: Always route IV set tubing and AC Power Adaptor cabling to prevent patient hazard or entanglement. Identify the individual IV set lines when multiple pumps and routes of administration are practiced.



Double Rotating Pole Clamp Assembly

SIGMA Part Number (P/N) 35743

- The double rotating feature of Double Rotating Pole Clamp enables the pump to be offset on left or right side of the single (standard) IV pole diameters ranging from 0.75” to 1.25”.
- The clamp can also be clamped to hospital bedside rail diameters ranging from 0.75” to 1.25”.
- Mount the clamp on the IV pole by rotating the triangular knob clockwise. The cylindrical protrusion on the triangular knob helps to rotate the knob faster.
- The pump mounted on the adaptor can be rotated clockwise or counterclockwise in 90° increments by pressing the lever located on the arm.
- The pump can be offset by the length of the arm by rotating the arm in clockwise or counterclockwise in 90° increments by pressing the lever located on the body of the clamp.
- Make sure the pump is in vertical orientation with the key hole at the top of the pump while in operation.
- Refer to the cleaning section of this manual for compatible cleaners.
- Refer to the installation manual, P/N 41092 on how to install the clamp on the pump.
- The weight of the clamp is less than 1.2 lbs.
- The dimension of the clamp is less than 7.0” long X 2.5” high X 4.5” wide.

CAUTION: Always operate the pump in vertical direction with the key hole at the top of the pump.

APPENDIX A - SPECIFICATIONS

Drug Error Prevention

“A” pump

- Includes Drug Library
- Prevents wrong dose rate mode and dose rate

“C” pump

- Includes Drug Library
- Prevents wrong dose rate mode and dose rate
- Includes Wireless Battery Module for wireless communication

Master Drug Library (MDL)

- PC based, pharmacy edited and controlled, customized in-house list of all IV and epidural drugs, along with their safe delivery parameters
- Care area enable:
  - same name/same concentration drugs to have different dose rate limits
  - pump configurations for maximum; rate, VTBI, patient weight and occlusion level
- Each drug entry includes the care area, drug name, concentration, dose rate mode, bolus mode, starting dose rate, soft (able to be exceeded) and hard (not able to be exceeded; an optional setting) dose rate and bolus limits, volume to be infused (VTBI), primary or secondary IV container, and pump screen color.

Drug Library Transfer

- Transfer from a wireless network connection to a pump using a wireless battery module
- Transfer from the PC directly to a pump via IrDA®

Standard Gravity IV Sets

Standard gravity IV sets from Baxter or Hospira.

Standards

- IEC60601-1 including collateral standards; Third Party Notified Body Testing (Reference Electromagnetic Compatibility Tables)

- IrDA® Serial Infrared Physical Layer Link Specification v1.4(IrPHY), IrDA Serial Infrared Link Access Protocol v1.1 (IrLAP) and IrDA Serial Infrared Link Management Protocol v1.1 (IrLMP), IrDA Tiny TP v1.1
- Wireless – 802.11b, 802.11g
- EIA-RS-232 levels for Asynchronous Transmit/Receive only (RS232)

<table>
<tr><th>Specification</th><th>Description</th></tr>
<tr><td>Overall Size (Pump)</td><td>With Standard Battery
Without IV pole clamp – 5.8” H x 4.2” W x 2.5” D
With IV pole clamp – 5.8” H x 6.4” W x 4.7” D
With Wireless Battery Module
Without IV pole clamp – 6.3” H x 4.2” W x 2.5” D
With IV pole clamp – 6.3” H x 6.4” W x 4.7” D</td></tr>
<tr><td>Weight</td><td>With Standard Battery
Without IV pole clamp – 25.5 oz ± 1.0 oz
With IV pole clamp – 33.5 oz ± 1.0 oz
With Wireless Battery Module
Without IV pole clamp – 26.5 oz ± 1.0 oz
With IV pole clamp – 34.5 oz ± 1.0 oz</td></tr>
<tr><td>Volumetric Accuracy</td><td>Accuracy is based on volume collected over one hour using compatible Baxter and Hospira Standard IV Sets.<table><tr><th></th><th>BAXTER</th><th>HOSPIRA</th></tr><tr><td>0.5 – 1.9 mL/hr</td><td>±0.1mL/hr</td><td>±0.1mL/hr</td></tr><tr><td>2.0 – 800 mL/hr</td><td>±5%</td><td>±5%</td></tr><tr><td>801 – 999 mL/hr</td><td>±5%</td><td>±10%</td></tr></table>Specified accuracy is maintained on Baxter Standard IV Sets for up to 96 hours (maximum 12 liters) and on Hospira Standard IV Sets for up to 72 hours (maximum 9 liters)</td></tr>
<tr><td>Infusion Modes</td><td>Continuous primary and secondary, Multi-Step, Cyclic TPN, Amount/Time</td></tr>
</table>

Specification	Description
Dose Modes	mL/hr, g/hr, mg/hr, mg/kg/hr, mg/min, mg/kg/min, mcg/hr, mcg/kg/hr, mcg/min, mcg/kg/min, ng/min, ng/kg/min, Units/hr, Units/kg/hr, Units/min, Units/kg/min, mUnits/min, mEq/hr, mEq/kg/hr, mUnits/kg/min, mUnits/kg/hr
Flow Rate	0.5 to 999 mL/hr with 0.1 mL/hr increments from 0.5 to 99.9 mL/hr and 1.0 mL/hr increments from 100 to 999 mL/hr
KVO	MDL drug configured KVO rate (default rate of 1.0 mL/hr if not configured) or programmed rate (whichever is less)
Total Drug Delivered	0.1 to 9999 mL with 0.1 mL increments from 0.1 to 99.9 mL and 1.0 mL increments from 100 to 9999 mL
Timekeeping	Real Time Clock, battery backed, 10-year life *NOTE:* Clock is set to GMT.
Logging Memory	■ AC Power Adaptor, low ■ 24 hr memory of all set up screens except for multi-stepand cyclic modes that are maintained permanently ■ Separate pump history log and drug event log ■ 10,000 ± event capacity. Once the maximum number of log entries is reached, the data for each new event replaces the data for the oldest event (the data for oldest event is lost)
AC Power	AC Power Adaptor, low profile, covers only one outlet, Medical Grade (EN60601-1-2): ■ Input: 100V-AC-240V-AC, 50-60Hz/200mA ■ Output: 9V-DC/800mA, short circuit protected ■ cord length 3.0 m (~ 9.75 feet) Use only SIGMA part number 35714 or equivalent The SIGMA Spectrum Infusion Pump is classified according to Medical Electrical Equipment standards as: ■ Class II Equipment ■ Type BF Applied Part ■ Continuous Operation
AC Power Adaptor and Protector	Weight 9.7 oz ±0.5 oz.

Specification	Description
Battery Power and Capacity	Standard Battery ■ Lithium Ion, 1800 mA/h, 7.4V nominal. SIGMA Part Number, 35724 ■ Capacity 8hrs (at 125 mL/hr at the highest backlight settings) ■ 12 hr. recharge time ■ Charging occurs if AC Power Adaptor is plugged in whether pump is ON or OFF Wireless Battery Module (802.11b) ■ Lithium Ion, 1800 mA/h, 7.4V nominal. SIGMA Part Number, 35083 ■ Capacity 4 hrs (at 125 mL/hr at the highest backlight settings) ■ 16 hr. recharge time ■ Charging occurs if AC Power Adaptor is plugged in, whether pump is ON or OFF Wireless Battery Module (802.11b/g) ■ Lithium Ion, 1800 mA/h, 7.4V nominal. SIGMA Part Number, 35162 ■ Capacity 4 hrs (at 125 mL/hr at the highest backlight settings). ■ 16 hr. recharge time ■ Charging occurs if AC Power Adaptor is plugged in, whether pump is ON or OFF
Pumping Mechanism	Linear peristaltic
Display	Color (16 out of a palette of 262,144 possible colors) HRTFT, 240 X 270, LED Front-Lit, 0.2235 mm X 0.2235 mm dot pitch
Occlusion Pressure	Adjustable: High (19 ±9 PSI), Medium (13 ±6 PSI), and Low (6 ±4 PSI)
Maximum Pump Pressure	28 PSI

Specification	Description
Operational Conditions	With Standard Battery ■ Operating temperature: 60 to 90°F (15.6 to 32.2° C), 20 to 90% relative humidity non-condensing With Wireless Battery Module ■ Operating temperature: 60 to 80°F (15.6 to 26.7° C), 20 to 90% relative humidity non-condensing
Storage Temperature	With Standard Battery ■ Storage temperature: -4 to 120°F (-20 to 49°C), 10 to 90% relative humidity non-condensing With Wireless Battery Module ■ Storage temperature: -4 to 120°F (-20 to 49°C), 10 to 90% relative humidity non-condensing

Specification	Description
Alarms and Alerts	■ Air-In-Line: dual beam ultrasonic detector alarms for large bubbles but allows smaller bubbles to pass. Detects air bubbles > 1" (» 125µL Hospira, » 140µL Baxter), will alarm if > 1 mL* of air in 15 min., < 50µL bubbles are omitted in the summation of the 1 mL.* *up to 1.5mL at 60°F ■ Audio: speaker actuated audio alarm, low, medium and high levels selected through the User Settings, Alarm Settings screen ■ Battery Missing – pump does not detect battery attached ■ Depleted Battery: pump stops running, alarms for 3 minutes ■ Dose Rate Limit Exceeded: the pump will run with a soft dose rate exceeded after a double confirmation, it will not run with a hard dose rate exceeded, rates must be reset within hard limits ■ Downstream Occlusion: automatic restart occurs after the downstream occlusion is cleared. Actuation can be set to Low, 6 ± 4 PSI, Medium, 13 ± 6 PSI or High, 19 ±9 PSI ■ Inactivity: actuates after the pump has been inactive for 2 minutes ■ Infusion Complete: occurs when the VTBI reaches zero, at which time a KVO rate begins (The previous running rate or 1 mL/hr, whichever is lower) ■ In Stop – Load Set ■ In Stop – Open Slide Clamp ■ In Stop – Push Run ■ Low Battery - < 30 minutes of battery power remain ■ Shut Door ■ Slide Clamp Closed – Pump Stopped ■ System Error ■ Upstream Occlusion ■ Very Low Battery - <15 minutes of battery power remain ■ Due for inspection: Preventative Maintenance and/or Network Certification
Alarm Volume	Variable (three levels: high, medium and low)

Specification	Description
Anti-Free-Flow System	Set based, utilizing IV set slide clamp.
Wireless Network Interface	Wireless Battery Module (802.11b), SIGMA Part Number 35083 ■ Standard: IEEE 802.11b ■ Transmit power: 16 dBm typical Wireless Battery Module (802.11b/g), SIGMA Part Number 35162 ■ Standard: IEEE 802.11b/g ■ Transmit Power: 12 dBm typical
Wireless Security	WEP (Wired Equivalent Privacy) ■ Encryption: 64/128-bit (RC4) WPA/WPA2/802.11i ■ Encryption: TKIP, CCMP (AES) ■ WPA-PSK ■ 802.1X authentication ■ LEAP (WEP only) ■ PEAP/MSCHAPv2 ■ EAP-TLS
External Interfaces	IrDA (SIR Encoding Protocol. Supports IrOBEX). Additional Asynchronous Serial Port expansion bus available at battery terminals. Software upgrades may be performed through external RS-232.

APPENDIX B - FLOW RATE ACCURACY

Effect of Fluid Container Height [1], [2]

The performance of the infusion pump will be influenced by the forces of gravity on the fluid being administered to the patient. When a fluid container is positioned above or below the patient's administration site, pressure forces associated with the fluid's head-height (distance measured from the center of the pumping mechanism to the top of the fluid in the source container) will cause deviations in the nominal specification for device flow rate accuracy. The nominal head-height used for the flow rate specification is 24" (±61 cm).

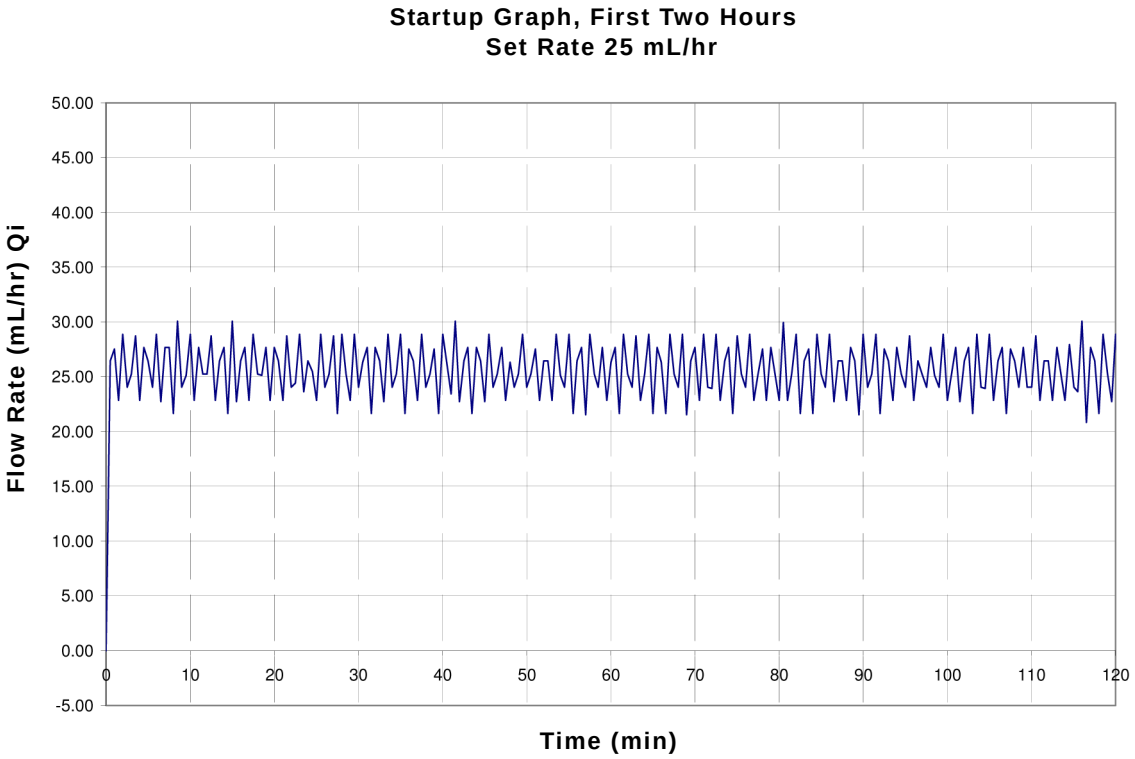
Effect of Back Pressure

Positive back pressure can influence the flow rate accuracy of the infusion. Back pressure equivalent to 300 mmHg may reduce the flow rate causing a deviation in accuracy by -9%. Negative back pressure of -100 mmHg may increase flow rate causing a deviation in accuracy of 7% Hospira and 3% Baxter IV Sets.

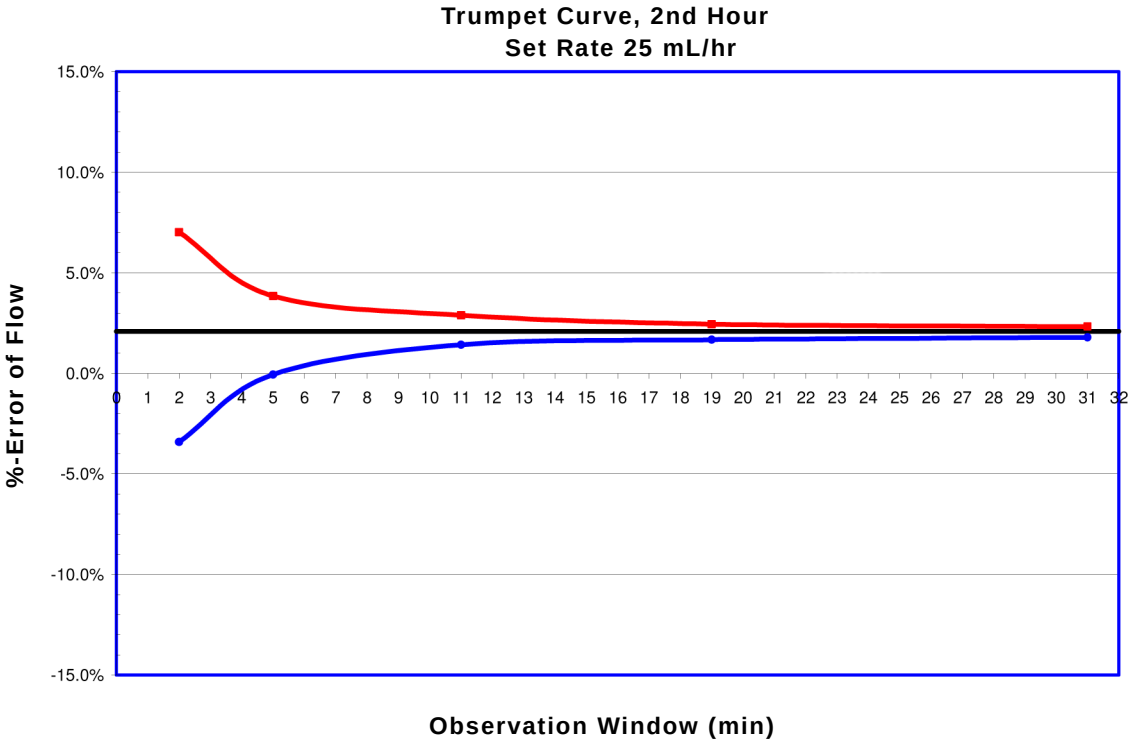
Flow Profile

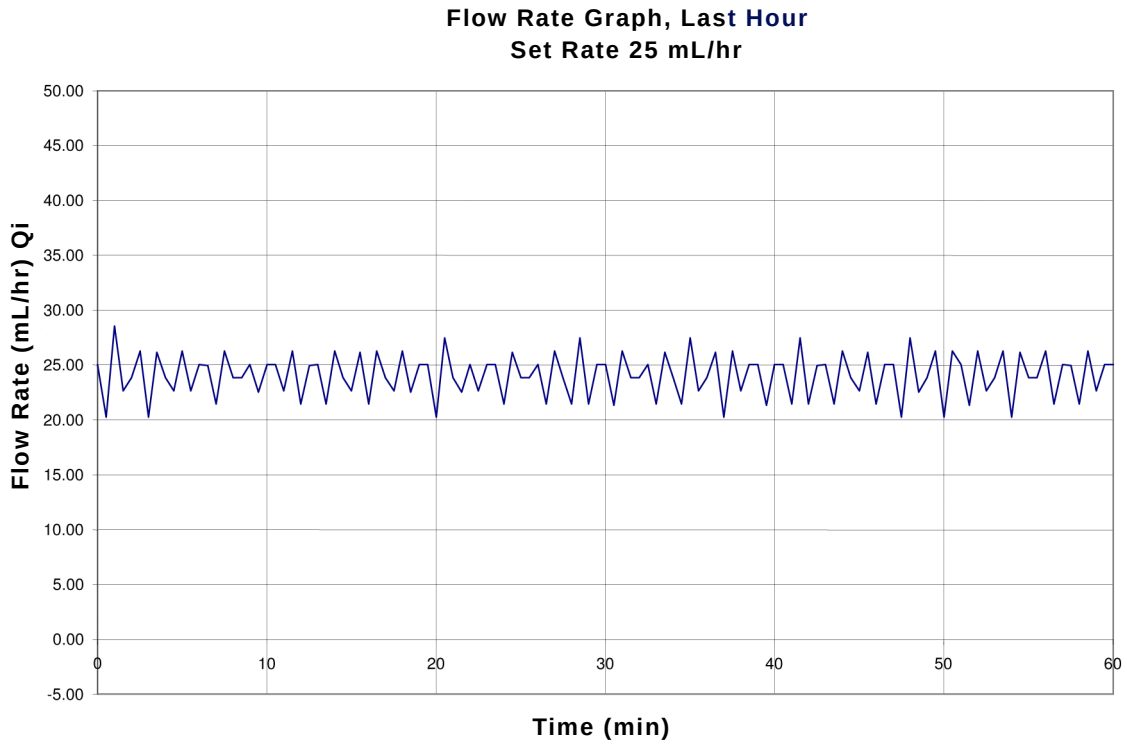
The SIGMA Spectrum Infusion pump has the following start-up flow rate accuracy curve shape associated with stability through time. These graphs represent the variation in flow rate that is recorded from the time the infusion is started to the end of a two hour period. The graph is intended to give a picture of the "general stability" with time of the infusion. The graph is commonly called a "start-up curve". The techniques and methods of test and generation of this graph are as detailed in IEC 60601-2-24, *Medical electrical equipment – Part 2-24: Particular requirements for the safety of infusion pumps and controllers*.

1.REFERENCE: AAMI ID26:1998, SUB-CLAUSE 50.102
2.LIQUID CONTAINER MUST BE VENTED OR A COLLAPSIBLE BAG

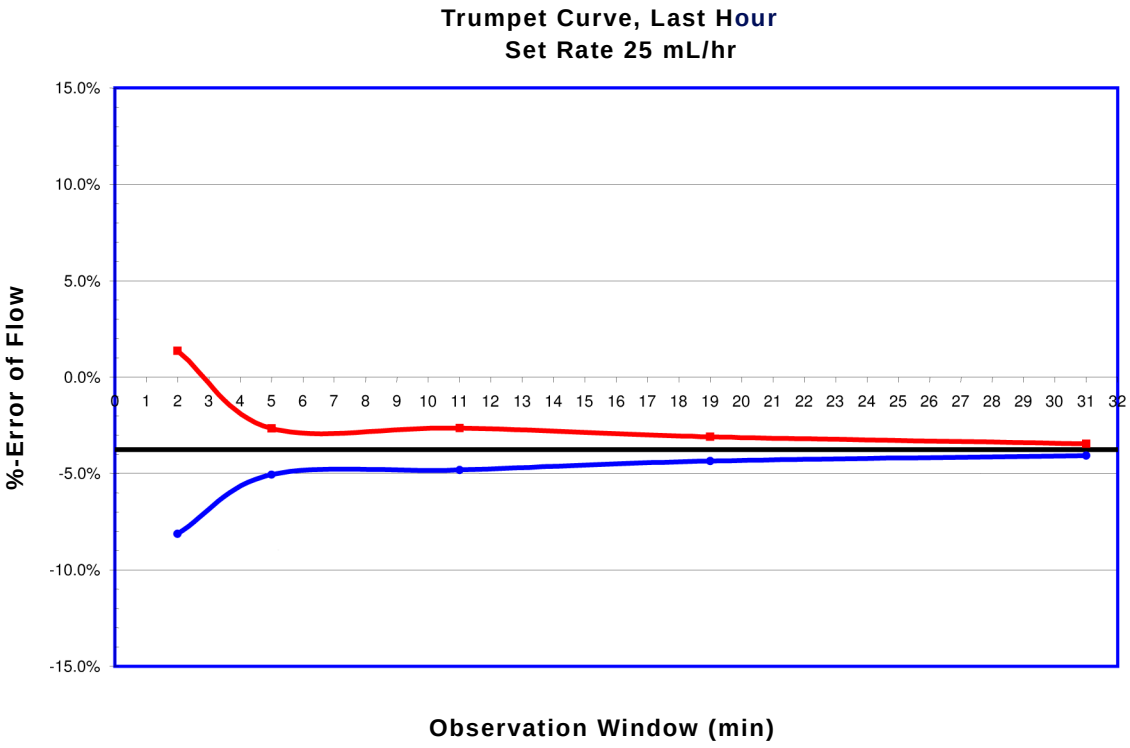


The percent variation of mean flow rate accuracy over a specific observation period may be quantified with the use of a trumpet graph. Using the rationale for development of a statistical trumpet graph as defined in IEC 60601-2-24, a presentation of the SIGMA Spectrum mean flow over a specific measurement interval is provided.


Trumpet Curve, 2nd Hour
Set Rate 25 mL/hr
%-Error of Flow
15.0%
10.0%
5.0%
0.0%
-5.0%
-10.0%
-15.0%
0 1 2 3 4 5 6 7 8 9 10 11 12 13 14 15 16 17 18 19 20 21 22 23 24 25 26 27 28 29 30 31 32
Observation Window (min)



Typical of intermediate rate last* Hr Flow Accuracy



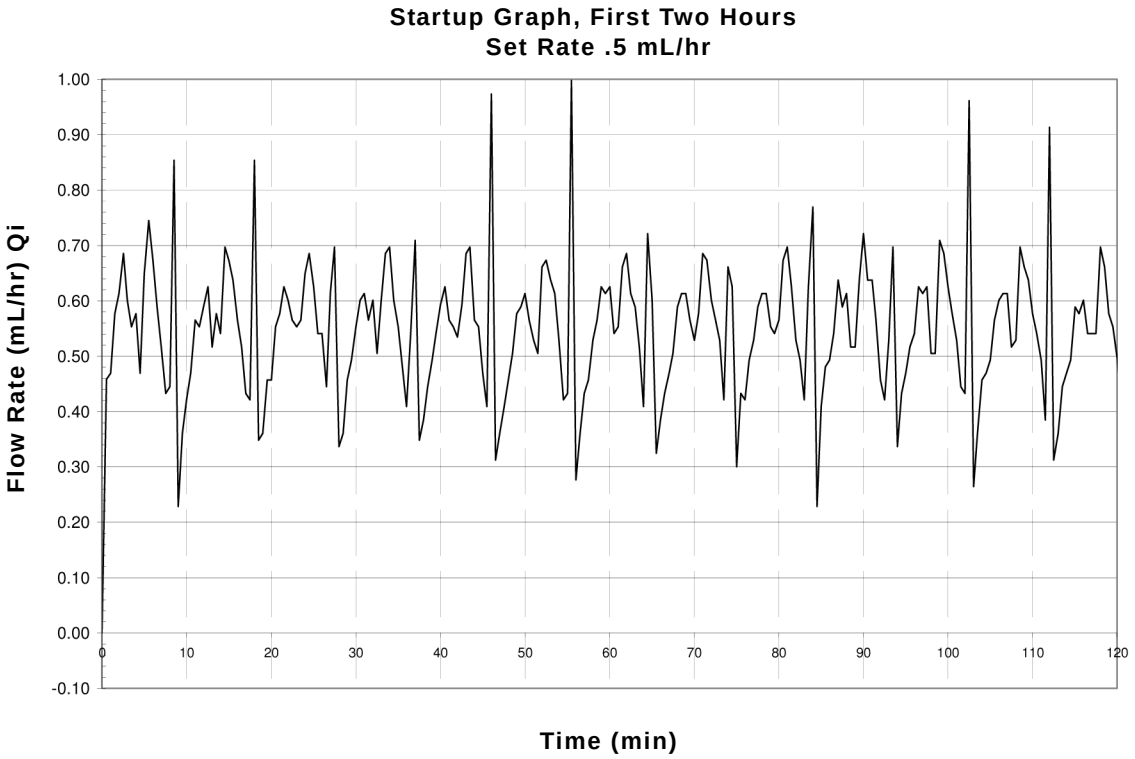
Typical of intermediate rate last* Hr, Trumpet Graph

NOTE: For Hospira calibration the last hour is the 72nd hour. For Baxter calibration the last hour is the 96th hour.

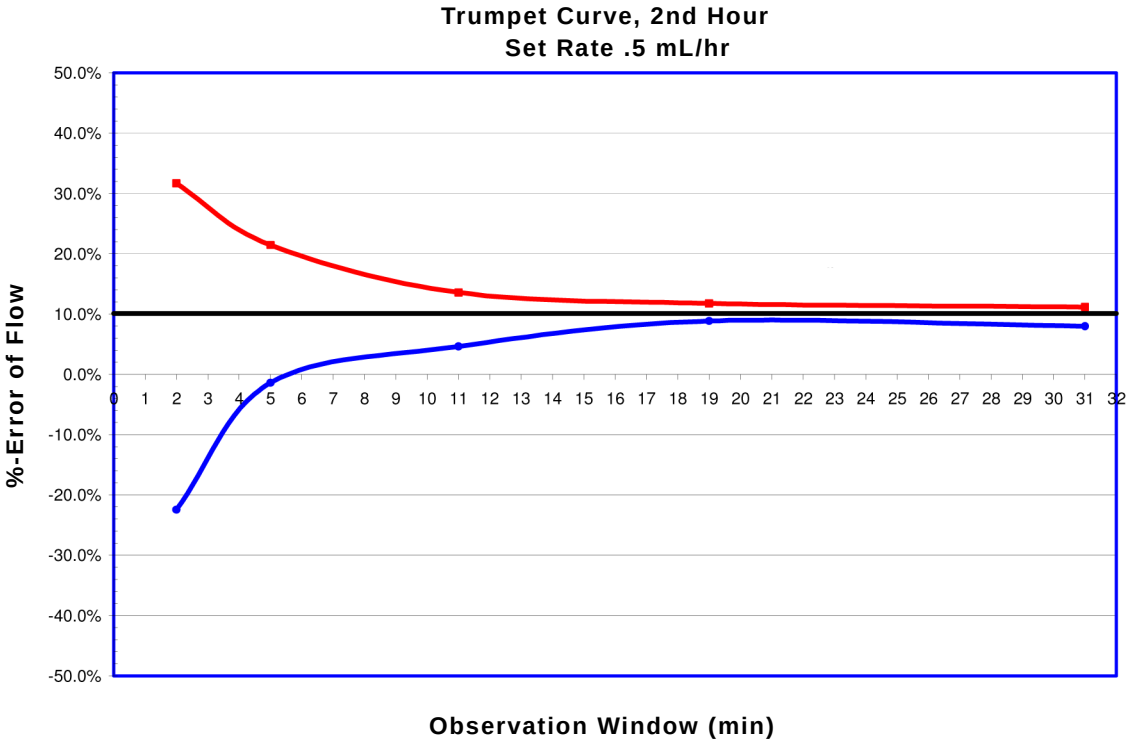
It is important for the clinician to understand the pharmacological influence of specific drugs based on concentrations and patient response when used in conjunction with the SIGMA Spectrum.

Pumping mechanisms produce fluctuation in fluid flow by design based on the specific mechanism type (peristaltic, piston, rotary, etc.), electronic control system and other factors related to the administration set's characteristics. Specific flow profiles are helpful in determining the correct clinical application for the infusion pump. Data is presented as requested by the applicable standards and represents the typical flow rate function of the Spectrum pump for short and long term operation. To help with the visualization of the flow inconsistencies that are typical of most infusion pumps, the start-up graphs and trumpet curves are extended to include the minimum rate (.5mL/hr) and intermediate rate (25 mL/hr) for the SIGMA Spectrum.

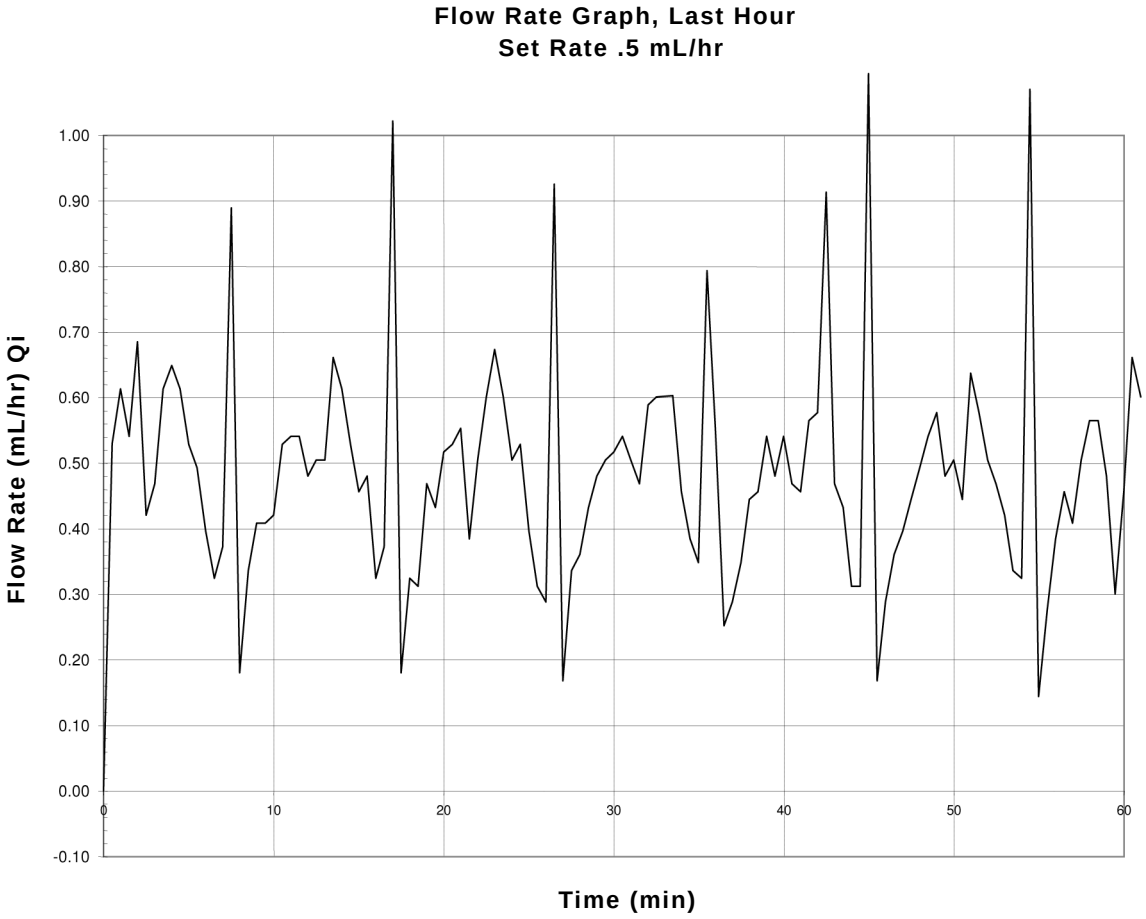
NOTE: The SIGMA Spectrum is best classified as a "Volumetric Infusion Pump" as defined by the applicable standards. Reference IEC 60601-2-24 and AAMI ID26:1998, Medical electrical equipment – Part 2: Particular requirements for safety of infusion pumps and controllers.



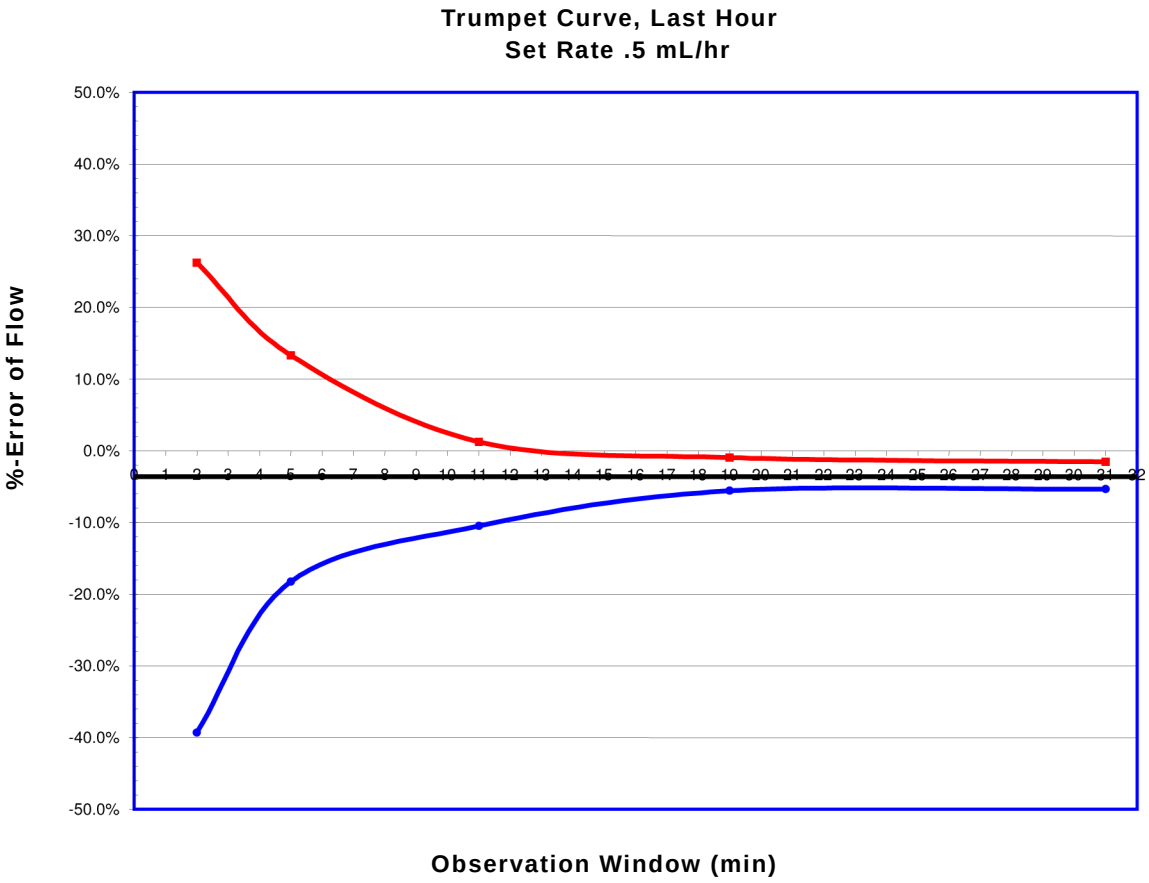
Typical of minimum rate start-up, flow rate



Typical of minimum rate 2nd Hr, Trumpet Graph



Typical of minimum rate last* Hr Flow Accuracy



Typical of minimum rate last* Hr, Trumpet

NOTE: For Hospira calibration the last hour is the 72nd hour.
For Baxter calibration the last hour is the 96th hour.

APPENDIX C - BOLUS ACCURACY

The SIGMA Spectrum IV Pump may have an optional bolus mode of operation. This feature allows the user to perform a BOLUS SETUP action. To utilize this feature the pump must be programmed with either a specific rate or a specific amount to be delivered in a certain amount of time.

If the pump is currently operating in mL/hr delivery mode, the bolus rate value is entered in mL/hr and the volume is entered in milliliter (mL). If the pump is operating in a non-mL/hr delivery mode (for example mcg/kg/min), the bolus amount would be entered in mcg/kg however the mL/HR soft-key may be pressed in the setup screen to enter the bolus information in mL/hr format.

In either mode, the time is entered in minutes and seconds (min:sec). Limits are placed on the minimum and maximum amount of time for the bolus delivery. The limit constraints are contained within the software of the Spectrum pump and are necessary to control the maximum or minimum flow rate of the bolus infusion.

The accuracy of the bolus volume is dependent on the resultant flow rate that is obtained from the calculation of volume to be delivered in the time requested. For example if the maximum bolus volume is 300 mL, the maximum flow rate is obtained with a bolus time of 18:01 (min:sec) or a flow rate of approximately 999 mL/hr. Using this maximum bolus volume, and delivering the volume in the shortest amount of time, the mean value of 300 mL ± 5% may be expected. Whereas using a minimum bolus volume (.5 mL), and delivering the volume in a short amount of time (1 minute), the mean value of .5 mL ±16% may be expected.

APPENDIX D - DOWNSTREAM OCCLUSION

Time to Occlusion

The maximum time for activation of the downstream occlusion alarm at the minimum flow rate of 0.5mL/hr is 1 hour at the minimum occlusion threshold setting. It is 3 hours at the maximum occlusion alarm threshold setting.

The maximum time for activation of the downstream occlusion alarm at the intermediate flow rate of 25mL/hr is 50 seconds at the minimum occlusion threshold setting. It is three minutes at the maximum occlusion alarm threshold setting.

Bolus Volume

The maximum bolus volume generated as a result of operation at 25 mL/hr and reaching the minimum downstream occlusion alarm threshold is 0.25mL.

The maximum bolus volume generated as a result of operation at 25 mL/hr and reaching the maximum downstream occlusion alarm threshold is 0.8mL.

CAUTION: Specifications for Downstream Occlusion detection times and bolus volume, after release of occlusion, are based on specific test conditions. The analytical related conditions are:

- A distance of 48” from the point of the downstream occlusion to the SIGMA Spectrum’s Downstream Occlusion sensor (approximately the distance from the IV administration set’s exit from the pumping channel to the point of occlusion).
- The 48” test administration set contained one “y”-site (no filters, or other components).
- Testing was at the nominal room temperature (72°F ±2°F).

Time to Downstream Occlusion and Bolus Volume release will generally increase under the following conditions: longer distances to the occlusion point, additional fluid volumetric area (from filters or other components within the IV set length) and hotter room temperatures.

APPENDIX E - ELECTROMAGNETIC COMPATIBILITY

Emissions

WARNING: The use of accessories or cables other than those specified by SIGMA may result in increased Emissions or decreased Immunity of this medical device.

Guidance and manufacturer's declaration – electromagnetic emissions		
The SIGMA Model Spectrum Infusion pump is intended for use in the electromagnetic environment specified below. The customer or user of the Spectrum should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The Spectrum uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The Spectrum is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Immunity – ESD, transient/burst, voltage disparity, magnetic

Guidance and manufacturer's declaration – electromagnetic immunity			
The SIGMA Model Spectrum Infusion pump is intended for use in the electromagnetic environment specified below. The customer or user of the Spectrum should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ± 15 kV air	±2 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%. See Note 1.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ±1 kV for input/ output lines	± 2 kV for power supply lines Not applicable	Supply power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode Not applicable	Supply power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % 120 VAC (>95 % dip in 120 VAC) or 0.5 cycle 40 % 120 VAC (60 % dip in 120 VAC) for 5 cycles 70 % 120 VAC (30 % dip in 120 VAC) for 25 cycles <5 % 120 VAC (>95 % dip in 120 VAC) for 5 sec	<5 % 120 VAC (>95 % dip in 120 VAC) or 0.5 cycle 40 % 120 VAC (60 % dip in 120 VAC) for 5 cycles 70 % 120 VAC (30 % dip in 120 VAC) for 25 cycles <5 % 120 VAC (>95 % dip in 120 VAC) for 5 sec	Supply power quality should be that of a typical commercial or hospital environment. If the user of the Spectrum requires continued operation during power interruption, it is recommended that the Spectrum be powered from an uninterruptible power supply or the internal battery be fully charged to provide unit power as specified in this operator's manual.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	400 A/m	400 A/m	Power frequency magnetic fields should be at levels characteristic of a typical commercial or hospital environment.

Note1: For levels 2, 3 & 4 a clearable alarm will occur with interruption of flow.

WARNING: The Spectrum pump is not designed to be MRI-compatible nor is it intended to be used in this manner. Strong magnetic fields (those beyond the level tested) may cause the device to operate improperly.

Do not expose the SIGMA Spectrum to strong magnetic fields such as is common with MRI equipment. Doing so may cause injury to the patient and/or damage to the equipment.

Immunity – Conducted and Radiated

Guidance and manufacturer's declaration – electromagnetic immunity			
The SIGMA Model Spectrum Infusion pump is intended for use in the electromagnetic environment specified below. The customer or user of the Spectrum should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compli-ance level**	**Electromagnetic environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the Spectrum, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz in ISM bands a	3 Vrms	$d = 1.2\sqrt{P}$
	10 Vrms 150 kHz to 80 MHz in ISM bands [a]	10 Vrms	$d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.5 GHz	10 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [c] should be less than the compliance level in each frequency range. [d] Interference may occur in the vicinity of the equipment marked with the following symbol: : "This excludes the Wireless Battery Modules, SIGMA Part Number 35083 and 35162"

Note 1 At 80 MHz and 800 MHz, the higher frequency range applies.
Note 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.756 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

[b] The ISM compliance level in the ISM frequency band between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason an additional factor of 3K is used in calculating the recommended separation distance for transmitters in these frequency ranges.

[c] Field strength from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radio, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Spectrum is used exceeds the applicable RF compliance level above, the Spectrum should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Spectrum.

[d] Over the frequency range 150 kHz to 80 MHz, field strength should be less than 3 V/m.

Immunity – Separation Distances

Recommended separation distance between portable and mobile RF communications equipment and the Spectrum

The SIGMA Model Spectrum is intended for use in an electromagnetic environment in which the RD disturbances are controlled. The customer or user of the Spectrum can help prevent electromagnetic interference by maintaining a minimum distance between the portable and mobile RF communications equipment (transmitters) and the Spectrum as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m			
	150 kHz to 80 MHz outside ISM bands $d = 1.2\sqrt{P}$	150 kHz to 80 MHz in ISM bands $d = 1.2\sqrt{P}$	80 MHz to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.12	.23
0.1	0.38	0.38	0.38	.73
1	1.2	1.2	1.2	2.3
10	3.8	3.8	3.8	7.3
100	12	12	12	23

For transmitters rated at maximum output power not listed above, the recommended separation distance *d* in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where power *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.756 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.

NOTE 3 An additional factor of 10/3 is used in calculating the recommended separation distance for the transmitters in the ISM frequency band between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.

NOTE 4 The guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

WARNING: The Spectrum pump is not designed to be exposed to linear accelerator radiation nor is it intended to be used in this manner. Exposure to radiation of this type may cause the device to operate improperly.

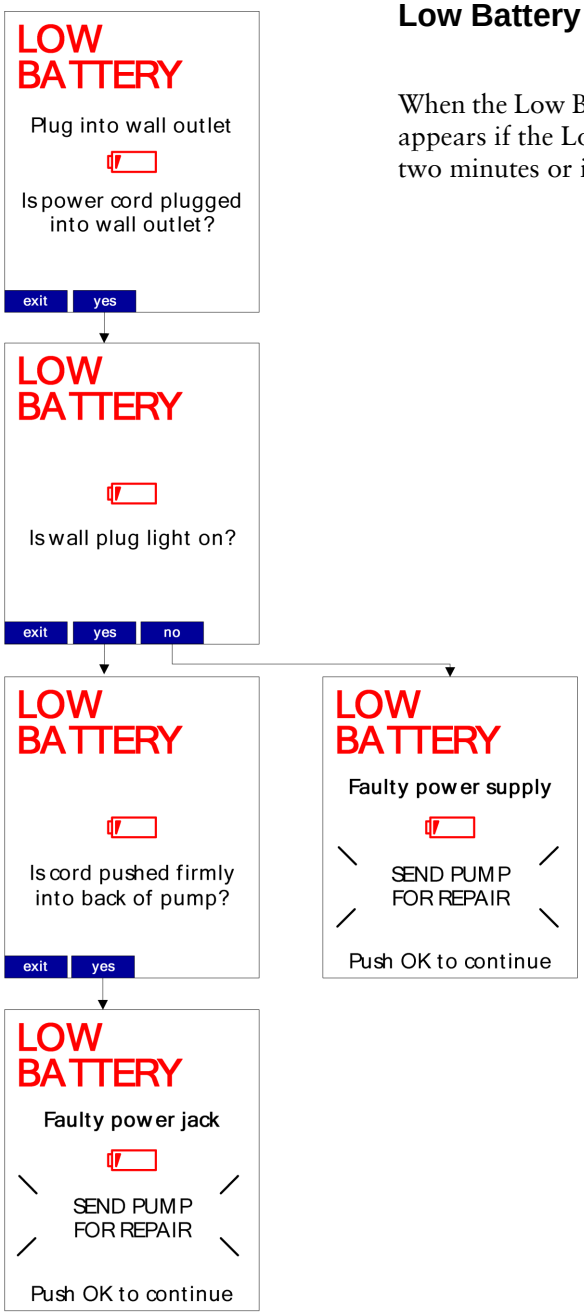
Do not expose the SIGMA Spectrum to linear accelerator radiation. Doing so may cause injury to the patient and/or damage to the equipment.

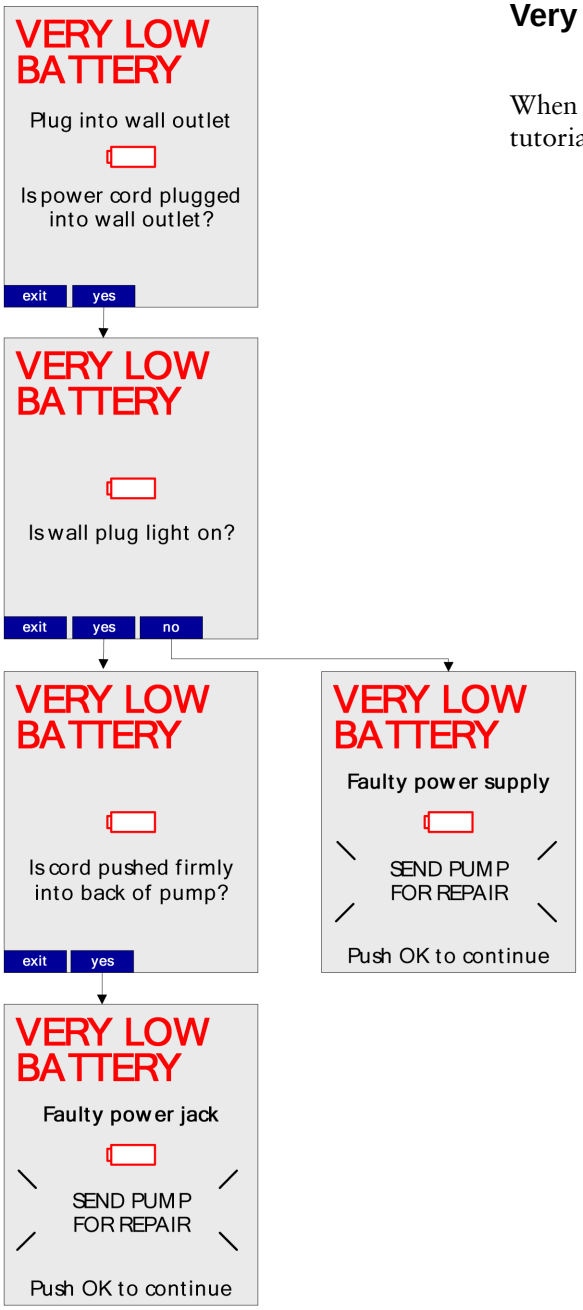
APPENDIX F - LOW / VERY LOW BATTERY TUTORIAL

The Low Battery and Very Low Battery Tutorials provide step-by-step confirmation that the external power supply is connected to the wall outlet, the power light is illuminated, and the power cord is properly connected to the Spectrum.

Low Battery Tutorial

When the Low Battery Alarm activates, the following tutorial appears if the Low Battery Alarm is not acknowledged after two minutes or if the **HELP** softkey is pressed.





Very Low Battery Tutorial

When the Very Low Battery Alarm activates, the following tutorial appears.

APPENDIX G - ICONS

Power Icons

These icons are visible in the upper left corner of the pump display.

Battery is 25% charged

Battery is 50% charged

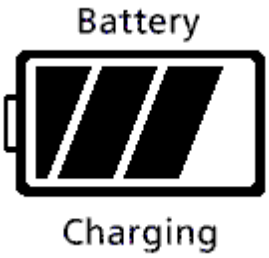
Battery is 75% charged

Battery is 100% charged

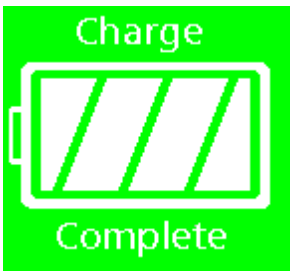
Battery is installed and the AC adaptor is connected. Alternates between one of the battery levels above.

Battery is depleted (Red battery)

Wireless Battery Module Icons



Wireless Battery Module is being charged. Battery segments (bars) animate from left to right. (Black battery; White background)



Wireless Battery Module is fully charged (White battery; Green background)

Battery Error. This will alternate with a battery code number if communication to the battery is functional. If communication to the battery is not functional the icon will be displayed without a battery code number. Refer to the Service Manual for a description of the error code. (Red battery)

AC power is supplied and battery pack is not installed. (Black battery)

Initial pump screen when AC power is supplied and the pump is powered off. Battery charger is determining the current status of the installed battery. (Black battery)

Wireless Icons

These icons are only visible when Wireless Battery Module is installed. They appear in the upper right corner of the pump.

Initializing; The dot will circle the tower. Events are not sent to the network host. (Red background)

Searching for the network and host. The "?" will toggle to the left and right of the tower while searching. Events will be sent to the network upon connection to the network host. (Yellow background)

Connected to host. Signals will radiate outward. Events are sent to the network host.(Green background)

Network disabled or Wireless battery removed. Events are not sent to the network host. (Gray background)

Network module error. Events are not sent to the network host.(inverting Red and White background)

A new drug library has been recieved the information and is ready for activiation. This icon can appear alongside any of the icon listed above.

The figure below shows the key lock and battery icon (upper left) and the network connection (upper right) icon.

Figure 19. Icon Displays

General Icons

The following icons are displayed on various screens in the Spectrum:

The "keypad lock" icon is shown in the upper left corner (above the power icon) of the display whenever the lock code has been entered to enable the keypad lock feature.

This icon shall be displayed next to any configuration option menu item (User or Biomed) whose setting has been assigned in the Master Drug Library to the currently selected drug. The word "option" will be displayed to the right of this image on any option that is an MDL-settable option and a drug has not yet been selected.

APPENDIX H - AMOUNT / TIME

Drug Amount / Time Infusion

This feature is only available when using MDL version 6.3.0 and later (not available in Basic or Multi-Step delivery modes).

Follow all set up, set loading/unloading and operation instructions in this manual.

To program a Drug Amount/Time Infusion:

1. Select Care Area. Press **OK**.
2. Type the drugs first two letters. all drugs beginning with those two letters will appear. Scroll to the desired drug. Press **OK**.
3. Use up and down arrow keys to select primary, secondary. If selected in the MDL, the required delivery mode will automatically display on the programming set up screen.
4. As selected in the MDL, one of the following set up screens will appear.

   4.1 **Fixed drug amount** - example: 500mg/100mL. These parameters may not be changed at the pump and represents the entire dose.

   4.1.1 Select and confirm concentration if more than one is displayed.
   4.1.2 Enter patient weight (kg) or BSA if required.
   4.1.3 Enter duration of infusion. Press OK.
   4.1.4 Dose (if weight based) is displayed.
   4.1.5 Infusion rate mL/hr is calculated and displayed.
   4.1.6 Press RUN to start the infusion.
   4.1.7 Check the flow and confirm that all clamps are open, there are no kinks in tubing, and drops are flowing. If everything is flowing properly, press the YES softkey.
   4.1.8 Press REVIEW softkey to display infusion status.
   4.1.9 Press STOP and REVIEW soft key to change mL/hr.

   4.2 **Standard concentration - drug amount/mL** - example: 10mg/mL as entered in the MDL. Infusion values are entered on the programming set up screen by the operator. The standard concentration may not be changed at the pump.

   4.2.1 Select and confirm drug amount per mL standard concentration if more than one is displayed.
   4.2.2 Enter drug amount. Press OK.
   4.2.3 VTBI is automatically calculated and displayed.
   4.2.4 Enter patient weight (kg) or BSA if required. Press OK.
   4.2.5 Enter duration of infusion. Press OK.
   4.2.6 Dose (if weight based) is displayed.
   4.2.7 Infusion rate mL/hr is calculated and displayed.
   4.2.8 Press **RUN** to start the infusion.

4.2.9 Check the flow and confirm that all clamps are open, there are no kinks in tubing, and drops are flowing. If everything is flowing properly, press the YES softkey.

4.2.10 Press REVIEW softkey to display infusion status while running.

4.2.11 Press STOP and REVIEW softkey to change mL/hr.

4.3 **Variable concentration** - Drug and mL amount are entered on the programming setup screen by the operator after the drug is selected.

4.3.1 Enter drug amount. Press OK.

4.3.2 Enter VTBI. Press OK.

4.3.3 Confirm admixture dialog prompt.

4.3.4 Enter patient's weight or BSA if required. Press OK.

4.3.5 Enter duration of infusion. Press OK.

4.3.6 Dose (if weight based) is displayed.

4.3.7 Infusion rate mL/hr is calculated and displayed.

4.3.8 Press RUN to start the infusion.

4.3.9 Check the flow and confirm that all clamps are open, there are no kinks in tubing, and drops are flowing. If everything is flowing properly, press the YES softkey.

4.3.10 Press REVIEW softkey to display infusion status.

4.3.11 Press STOP and REVIEW softkey to change mL/hr.

Priming Volume Adjustment for Primary Amount / Time Infusions Only

This feature is only available when using MDL version 6.5.0 and later.

This feature can be set per care area configuration (ON/OFF) in the MDL. It appears after all parameters are newly entered and after IV set load or reload. This feature allows adjustment (subtraction) of the mL amount used to prime the set from the initial drug amount, VTBI, and duration.

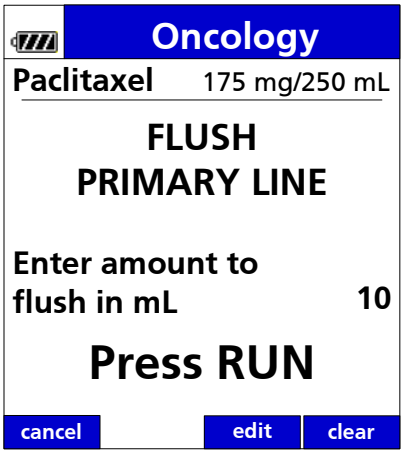
1. Press **YES** or **NO** softkey to accept/decline priming volume displayed or press **EDIT** softkey to change amount (mL).
2. Press **OK**.
3. Press **RUN**.

Flush

This feature is only available when using MDL versions 6.3.0 and later.

- Can be delivered in drug amount/time infusion modes (as selected in the Master Drug Library) and is not available in continuous modes.
- The maximum flush volume is 100 mL - up to 3 flushes allowed.
- The flush rate is the same as the last displayed mL/hr rate.
- Software versions 6.04 and later: A maximum flush volume between 1-100 mL can be entered in the MDL for each drug.

1. At primary or secondary infusion complete, rate KVO, press **STOP**.
2. Press **YES** to flush and enter flush volume (mL), or **NO** to reset the program.



3. At Line Flush Complete Screen (primary or secondary) press **STOP** and **REPEAT FLUSH** softkey, if necessary. To reset the program, press **NO** to flush prompt.